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Supreme Court, U.S.
FILED
AUG 09 2007
OFFICE OF THE CLERK

No. 07-35

IN THE

Supreme Court of the United States

APOTEX, INC., APOTEX CORP., AND NOVEX PHARMA,
Petitioners,

v.

SYNTEX (U.S.A.) LLC AND ALLERGAN, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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August 9, 2007

QUESTION PRESENTED

The district court issued 132 findings of fact and conclusions of law in support of its judgment that Respondents' patent was not obvious. The Court of Appeals affirmed that conclusion shortly before this Court issued its opinion in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), but well after the Court of Appeals had articulated the very standard this Court ultimately embraced in *KSR*. After this Court issued *KSR*, Petitioners moved to recall the mandate, presenting the Court of Appeals with every single argument they present here for why this Court's opinion in *KSR* could potentially change the result. The Court of Appeals rejected those arguments. Should this Court deny the Petition seeking to grant certiorari, vacate, and remand for the Court of Appeals to consider the impact of *KSR*, yet again?

CORPORATE DISCLOSURE STATEMENT

Respondent Syntex (U.S.A.) LLC is now known as Roche Palo Alto LLC and is a wholly owned subsidiary of Roche Holdings, Inc. No publicly held company owns 10% or more of the stock in Syntex.

FMR Corp. own 13.65%, UBS AG owns 11.56%, and Capital Group International, Inc. owns 10.98% of the stock in Respondent Allergan, Inc.

TABLE OF CONTENTS

QUESTION PRESENTED i

CORPORATE DISCLOSURE STATEMENT ii

INTRODUCTION 1

STATEMENT OF THE CASE 3

The Patented Formulations 3

The Proceedings Below 5

The Court's Opinion in KSR 7

The Motion to Recall the Mandate 10

REASONS TO DENY THE WRIT 10

I. THE COURT OF APPEALS FULLY CONSIDERED THIS COURT'S OPINION IN *KSR* AND ALL THE ARGUMENTS APOTEX NOW OFFERS BASED ON *KSR*. 11

A. The Court of Appeals Considered, and Embraced, Apotex's Argument that Prior Art from Other Fields Should Be Considered. 12

B. The Court of Appeals Considered, and Adopted, Apotex's Argument that Prior Art References Should Be Considered Even if they Address a Different Problem than the Patent. 13

C. The Court of Appeals and the District Court Considered, and Had Already Agreed with, Apotex's Argument that a Motivation to Combine Need Not be Found Explicitly in the Prior Art. 14

D. The Court of Appeals Must Have Rejected Apotex's Arguments on the Merits to Deny its Motion to Recall the Mandate. 16

II. THERE IS NO REASONABLE PROBABILITY THAT THE DECISION BELOW RESTS UPON A PREMISE THAT THE COURT OF APPEALS WOULD REJECT IF GIVEN THE OPPORTUNITY FOR FURTHER CONSIDERATION. 17

III. A GVR HERE WILL NOT CHANGE THE ULTIMATE OUTCOME OF THE LITIGATION. 20

A. A Redetermination on Remand Would Not Affect the District Court's Opinion that the Dependent Claims of the '493 Patent are Valid and Infringed. 21

B. A Redetermination on Remand Would not Affect the District Court's Findings that There Was Strong Evidence to Overcome any *Prima Facie* Showing that the Patent was Invalid. 23

IV. THE EQUITIES OF THE CASE COUNSEL AGAINST A GVR. 25

CONCLUSION 25

TABLE OF AUTHORITIES

Cases

Alza Corp. v. Mylan Labs., Inc.,
464 F.3d 1286 (Fed. Cir. 2006)..... passim

Cross Med. Prods., Inc. v. Medtronic Sofamar Danek, Inc.,
424 F.3d. 1293 (Fed. Cir. 2005).....18

DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.,
464 F.3d 1356 (Fed. Cir. 2006)..... passim

Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.
471 F.3d 1369 (Fed. Cir. 2006).....23

Graham v. John Deere Co. of Kansas City,
383 U.S. 1 (1966).....23

In re Lee,
277 F.3d 1338 (Fed. Cir. 2002).....19

KSR International Co. v. Teleflex Inc.,
127 S. Ct. 1727 (2007)..... passim

Lawrence v. Chater,
516 U.S. 163 (1996)..... passim

Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Company,
520 U.S. 893 (1997).....16

Pfizer, Inc. v. Apotex, Inc.,
480 F.3d 1348 (Fed. Cir. 2007).....20

Stratoflex, Inc. v. Aeroquip Corp.,
713 F.2d 1530 (Fed. Cir. 1983).....23

Stutson v. United States,
516 U.S. 193 (1996) 11, 16

Statutes

35 U.S.C. § 103 ..... 7, 8

35 U.S.C. § 271(e)(2) 5

35 U.S.C. § 282 21

Appendix Page

Reporter's Transcript of Audio Recording Transcription, U.S. Court of Appeals for the Federal Circuit, No. 06-1495 ..... 1a

Defendants-Appellants' Motion to Recall and Stay the Mandate 23a

Defendants-Appellants' Motion for Extension of Time to File Combined Petition for Panel Rehearing and Rehearing En Banc and Motion to Recall and Stay Mandate 28a

Appellees' Opposition to Appellants' Motion to Recall and Stay the Mandate, and for Extension of Time to Petition for Rehearing 34a

Defendants-Appellants' Reply to Appellees' Opposition to Appellants' Motion to Recall and Stay the Mandate, and for Extension of Time to Petition for Rehearing 50a

INTRODUCTION

Petitioners Apotex, Inc., Apotex Corp., and Novex Pharma (collectively, "Apotex") ask this Court to indulge them in a futile exercise. They want this Court to vacate a judgment of the Court of Appeals in order for it to consider arguments Petitioners already presented to the Court of Appeals and the Court of Appeals already rejected.

After five years of litigation, in 132 findings of fact and conclusions of law, the district court held that the patent-in-suit is not invalid for obviousness. Apotex appealed, and the Court of Appeals affirmed.

Apotex does not contend that this case qualifies for certiorari under the considerations set forth in Supreme Court Rule 10. This case presents no unsettled question of federal law, no circuit conflict, and no issue of profound national importance. Rather, Apotex asks the Court to issue an order granting certiorari, vacating, and remanding this case (a "GVR" order) to give the Court of Appeals the chance to reconsider its affirmance in light of *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Apotex's Petition fails under all four factors this Court considers in deciding whether to GVR.

First, the Court of Appeals already considered this case in light of this Court's intervening decision in *KSR*, and concluded it was unnecessary to change a thing. After the *KSR* opinion came down, Apotex brought a motion to recall the mandate in the Court of Appeals. The sole argument Apotex pressed was that *KSR* was inconsistent with the Court of Appeals' affirmance. Indeed, Apotex's motion in the Court of Appeals made the same arguments that it makes here in its Petition for Certiorari. After reading those arguments, the Court of Appeals denied Apotex's motion and did not recall its mandate. There is no reason to vacate

this case to allow the Court of Appeals to consider the same arguments yet again.

Second, there is no reasonable chance that *KSR* would lead the Court of Appeals to reach a different conclusion on the question of obviousness. This appeal was briefed, argued, and affirmed in light of recent Federal Circuit precedent that is wholly consistent with *KSR*. Moreover, the district court's opinion did not apply the "rigid" analysis—or any of the other errors—this Court criticized in *KSR*.

Third, even if the Court of Appeals reconsidered the district court's obviousness ruling in light of *KSR*, it would still have to affirm the district court. As an initial matter, the district court found that Apotex has never presented evidence that *other* claims of the same patent (the dependent claims) are invalid. The relief the district court granted must stand regardless of *KSR* because Apotex also infringed these other claims. Moreover, the most that *KSR* could affect was the conclusion of the district court that Apotex had failed to make out a *prima facie* case of obviousness. But *KSR* has no bearing on the district court's findings that Respondents had made a strong showing to overcome any *prima facie* case. So a GVR could not change the ultimate outcome of this litigation.

Finally, the equities of this case counsel strongly against a GVR. Respondents have already expended significant resources prosecuting this five year litigation. Given the low likelihood that a GVR would yield any different result, Respondents should not be required to expend further resources defending their patent.

STATEMENT OF THE CASE

The Patented Formulations

Respondent Syntex (U.S.A.) LLC ("Syntex") developed and patented a way of treating trauma caused by eye surgery, as well as glaucoma and other eye diseases or injuries associated with inflammation using a new formulation. This new formulation was composed, in pertinent part, of three elements: (1) a particular form and class of drug (a non-steroidal anti-inflammatory drug, or "NSAID" with a carboxyl group); (2) Octoxynol 40 (a surfactant, a compound that acts as a stabilizer); and (3) a particular class of preservative. Pet. App. 11a-13a. This combination yields a stable, clear, solution that is effective in treating a wide variety of diseases and conditions. Pet. App. 198a-99a.[1]

The Patent and Trademark Office issued U.S. Patent No. 5,110,493 ("the '493 patent") on May 5, 1992 to Syntex. Pet. App. 27a. The '493 patent was licensed to respondent Allergan, Inc. ("Allergan") who marketed the patented formulation under the name ACULAR®. The invention has enjoyed tremendous commercial success, with ACULAR® capturing a 36% market share among ophthalmic anti-inflammation drugs and generating $291 million dollars in sales between 1992 and 2001. Pet. App. 42a-44a, 61a-63a.

In an effort to demonstrate that Syntex's formulation was obvious—and that its patent is therefore invalid—Apotex rests entirely on one argument: "the substitution of one water-soluble, micelle-forming, nonionic surfactant called

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[1] The Petition for Writ of Certiorari is cited as "Pet.," and the Appendix to the Petition is cited as "Pet. App." The Appendix to this opposition is cited as "Res. App."

Octoxynol 40 ('O_{40}'), for another equivalent one called Polysorbate 80" was obvious. Pet. 1. Apotex's position before this Court, then, depends on three propositions: (1) that the substitution of one surfactant for the other was the only innovation; (2) that Octoxynol 40 was "equivalent to" Polysorbate 80, which is to say that Syntex made no improvement over pre-existing formulations; and (3) the substitution of the one surfactant for the other would have been obvious to any knowledgeable drug formulator. The district court rejected each of these propositions as a matter of fact, in extensive findings.

First, the district court found that the patented invention distinguished itself from preexisting formulations in numerous other ways. Pet. App. 15a-19a.

Second, the district court found that the surfactant Syntex used (Octoxynol 40) was superior to the preexisting alternative (Polysorbate 80, or "Tween 80"). Pet. App. 31a. The district court cited experimental proof from the time of the invention that the former surprisingly outperformed the latter. *Id.* The district court also rejected, as flawed, Apotex's much later experiments purporting to rebut this conclusion. Pet. App. 33a.

Third, on the issue of obviousness, there was no evidence Octoxynol 40 was ever used in an ophthalmic formulation—*i.e.*, as an eye medication—before Syntex devised the idea. Pet. App. 27a-29a. Apotex presented some evidence that the compound had been used in pharmaceuticals in general, and testimony that the compound had been used in cosmetics. But the district court gave this evidence little credence because Apotex never adduced any evidence of what those pharmaceutical or cosmetic products were or what the particular use of Octoxynol 40 in those unknown products might have suggested to one of ordinary skill in the art. Pet. App. 29a.

In fact, the district court found that Syntex had tried for many years to formulate a stable eye solution. It tried all sorts of stabilizers other than Octoxynol 40, all to no avail. Pet. App. 64a-65a, 161a. The district court also found that the fact that Octoxynol 40 worked better than other stabilizers was "unexpected." Pet. App. 173a-74a, 50a-54a.[2]

Needless to say, Apotex does not appeal these factual findings to this Court.

The Proceedings Below

With the '493 patent still in effect, Apotex filed an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of ACULAR®. In connection with the application, Apotex asserted that the '493 patent was not infringed and was invalid. In response, Allergan and Syntex brought this lawsuit. *See* 35 U.S.C. § 271(e)(2).

On summary judgment, the district court found that Apotex's product would, indeed, infringe the '493 patent. Then, after a three-week trial, the district court found that the '493 patent was valid. Pet. App. 107a-95a. The district court rejected Apotex's argument that Syntex's invention was obvious.

Apotex appealed. In a published opinion, the Court of Appeals affirmed the district court on all issues, except that it reversed and remanded for further consideration of obviousness. Pet. App. 70a-103a. Especially notable were

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[2] In reaching this conclusion, the district court considered Apotex's arguments based on the prosecution history of the '493 patent that Apotex presents again here (Pet. 5-8) and rejected them in 29 well-reasoned findings of fact and conclusions of law, none of which are at issue on this appeal. Pet. App. 19a-27a, 50a-54a.

two of the Court of Appeals' instructions to the district court on remand, for they were two of the same instructions this Court provided in its later-issued opinion in *KSR*. Both were about how the courts should consider prior art references—preexisting technology that is cited in support of an argument that a patented invention was obvious. First, the Court of Appeals instructed the district court that "what a reference teaches a person of ordinary skill is not, as Syntex's expert appears to believe, limited to what a reference specifically 'talks about' or what is specifically 'mentioned' in the reference." Pet. App. 86a-87a. Second, the Court of Appeals instructed the district court that it should not discount a reference merely because it does not address the same problem as that solved by the '493 patent. Pet. App. 88a. For example, a prior invention might still be relevant in proving obviousness, even if it was not used in an eye medication.

On remand, the district court did not commit these errors. Contrary to Apotex's assertions, (Pet. 9), the district court followed each of the Court of Appeals' instructions. Hence, the district court considered (1) evidence of the use of Octoxynol 40 in pharmaceuticals as well as testimony that it was used in cosmetics (Pet. App. 27a-29a); (2) that the prior art did not affirmatively teach people not to use Octoxynol 40 (Pet. App. 34a-35a, 55a-56a); (3) the testimony of Apotex's expert providing his theory on why the inventions would have been obvious (Pet. App. 35a-41a, 52a-54a, 58a-60a); and (4) the prosecution history (Pet. App. 19a-27a). The district court then concluded once again that Apotex had failed to prove the '493 patent invalid.

Apotex appealed again. This time there was no dispute about the legal standards. By the time the parties began briefing the appeal—in September, 2006—this Court had already granted certiorari in *KSR*, and, in response to this Court's signal, the Court of Appeals had already

rearticulated its standard of obviousness. *See Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). The parties on both sides of this dispute embraced this rearticulated standard in presenting their obviousness arguments before the Court of Appeals.

That left Apotex to quarrel exclusively with the district court's factual findings and to ask the Court of Appeals to reweigh the evidence and find the district court's factual conclusions clearly erroneous. The Court of Appeals noted this repeatedly at oral argument. Res. App. 3a ("What I'm still concerned about, you want us to reweigh the evidence on behalf of the lower court? The same evidence that was there before, you want us to reweigh. I mean, that's not our function."); Res. App. 5a ("Now, if we're reweighing this evidence, you just lost, didn't you?"); Res. App. 3a ("And you're asking us to reweigh again?"). Apotex did not deny that it had appealed only factual issues, answering, "[u]nfortunately, yes." *Id.*

The Court of Appeals affirmed on April 9, 2007, without waiting for this Court's imminent opinion in *KSR*. It was clear that Apotex could not satisfy any standard of obviousness. Although Apotex was aware that *KSR* was pending, it did not timely seek rehearing challenging any of the legal standards the district court had applied.

The Court's Opinion in KSR

This Court's opinion in *KSR* dealt with the standard for proving a patent invalid as "obvious" under Section 103 of the Patent Act. *KSR*, 127 S. Ct. at 1734-35. Section 103 provides that a patent is invalid as obvious when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103.

Proving that a patent "would have been obvious" under Section 103 usually means proving that, although there is no single prior invention or technology that contains all the features of the patented invention, there are two or more pieces of "prior art" that, when combined together, add up to the patented invention. Over the years, the Federal Circuit has developed the requirement that in order to prove a patent obvious in this way, the party accused of infringement has to show that there would have been a "teaching, suggestion, or motivation" to combine the two or more pieces of prior art to arrive at the patented invention. *KSR*, 127 S. Ct. at 1734. This is commonly referred to as the "TSM test." *Id.*

In *KSR*, the Court held that although "[t]here is no necessary inconsistency between the idea underlying the TSM test and [this Court's prior] analysis," the Federal Circuit erred in *KSR* by turning the TSM test into "rigid and mandatory formulas." *Id.* at 1741. In particular, the Court identified three specific errors that the Federal Circuit had made:

First, the Federal Circuit erred in *KSR* by "holding that courts and patent examiners should look only to the problem the patentee was trying to solve" in deciding whether a patent was obvious *Id.* at 1742. In other words, a person might be motivated to combine the prior art to solve a different problem than the problem addressed by the patent at issue. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Second, the Federal Circuit erred in *KSR* "in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." *Id.* The Federal Circuit erred in *KSR* because it concluded that an inventor would not have considered using one particular prior technology ("the Asano pedal") merely because the Asano pedal was not designed to solve the same problem as the invention at issue in *KSR*.

Third, the Federal Circuit erred in *KSR* because it refused to look beyond what the prior art references explicitly said to find a motivation to try combining the prior art. *Id.* The Federal Circuit refused to consider, for example, evidence in that case that there was a "design need or market pressure" to combine the prior art or that "common sense" would lead one to combine the prior art. *Id.*

The Court also made clear that courts should not restrict themselves to considering prior art references from the field of the patented inventions. *Id.* at 1740. "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." *Id.*

Although the Court reversed the Federal Circuit in *KSR*, it noted that "[i]n the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases." *Id.* at 1741. In particular, the Court noted that after the grant of certiorari in *KSR*, "the Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter." *Id.* at 1743 (citing *Alza Corp. v. Mylan Labs, Inc.*, 464 F.3d 1286 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367

(2006)). Both of these two cases cited by the Court were briefed to the Court of Appeals in the appeal below.

The Motion to Recall the Mandate

This Court decided *KSR* on April 30, 2007. Four days later, Apotex filed a motion asking the Court of Appeals to recall and stay its mandate in light of this Court's decision in *KSR*. Resp. App 23a-27a. The sole argument Apotex made in favor of its motion was that the opinion below was "incompatible with the Supreme Court's holding in *KSR*." Res. App. 24a. Apotex made every argument to the Court of Appeals that it makes to this Court in its Petition for Certiorari. Res. App. 50a-61a. In opposing the motion, Syntex and Allergan responded on the merits, arguing that because the district court's opinion complied with *KSR* there were no exceptional circumstances to justify recalling the mandate. Res. App. 43a-48a. The Court of Appeals denied Apotex's motion to recall the mandate, which can only mean that it was convinced that nothing in *KSR* affected the standards that it had already applied in affirming the district court. Pet. App. 3a-4a.

Nonetheless, Apotex petitions for certiorari, asking this Court to vacate the decision of the Court of Appeals and direct it to consider that same question once again.

REASONS TO DENY THE WRIT

The sole issue on this Petition is whether this Court should GVR in light of *KSR*. Apotex is not entitled to a GVR unless it can demonstrate four factors that it scarcely addresses in its Petition. Pet. 23-26. This Court has described those factors as follows:

> Where [1] intervening developments, or recent developments that we have reason to believe the court

> below did not fully consider, [2] reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and [3] where it appears that such a redetermination may determine the ultimate outcome of the litigation, a GVR order is, we believe, potentially appropriate. [4] Whether a GVR order is ultimately appropriate depends further on the equities of the case . . . .

Lawrence v. Chater, 516 U.S. 163, 167-68 (1996). This Court should deny Apotex's Petition because Apotex fails to satisfy any of these factors.

I. THE COURT OF APPEALS FULLY CONSIDERED THIS COURT'S OPINION IN *KSR* AND ALL THE ARGUMENTS APOTEX NOW OFFERS BASED ON *KSR*.

The core rationale for a GVR order is that "a GVR order both promotes fairness and respects the dignity of the Court of Appeals by enabling it to consider potentially relevant decisions and arguments that were not previously before it." *Stutson v. United States*, 516 U.S. 193, 197 (1996). Apotex argues that "[t]he relevant intervening *KSR* decision was not considered by the Federal Circuit or the district court." Pet. 25. This is incorrect.

Apotex has already argued to the Court of Appeals that the district court's opinion was "incompatible with the Supreme Court's holding in *KSR*" in its motion to recall the mandate. Res. App. 24a. Indeed, Apotex presented to the Court of Appeals in that motion each of the "three reasons" it now asserts in its Petition for Certiorari for why the district court's opinion was inconsistent with *KSR*. Pet. 13-16. Even if Apotex had not done so, we can be certain that the Court of Appeals had the correct standard in mind when it

reviewed the district court, because the Court of Appeals had previously directed the district court not to make the very mistakes that Apotex claims the district court made. It would make no sense to remand to the Court of Appeals to verify that it was applying a legal standard that it had already directed the district court to apply.

A. The Court of Appeals Considered, and Embraced, Apotex's Argument that Prior Art from Other Fields Should Be Considered.

First, Apotex argued to the Court of Appeals, as it argues now to this Court, that the district court's opinion was inconsistent with *KSR* in making the factual finding that none of the prior art references teach the use of Octoxynol 40 in ophthalmic formulations. Res. App. 55a-57a; *compare with* Pet. 13-14, 16. Apotex's claim, both here and before the Court of Appeals, is that merely by making this perfectly accurate factual finding, the district court violated this Court's instruction in *KSR* that courts should not refuse to consider prior art references because they are from a different field from the patent at issue. 127 S. Ct. at 1740.

Apotex even made this precise same argument – that the district court should consider prior art references from outside the field of ophthalmics (and indeed from outside the field of pharmaceuticals) – to the *district court* on remand from the first appeal in this case. And in determining nonobviousness on remand, the district court did not commit the error that the Court of Appeals had committed in *KSR*; the district court did not restrict itself to considering prior art references from the field of ophthalmics. In addition to the three prior art patents Apotex asserted from the field of ophthalmics, the district court considered all of Apotex's asserted prior art from other fields, including the field of pharmaceuticals in general, chemistry, and cosmetics. *See, e.g.*, Pet. App. 15a.

This was because, on the first appeal in this case, the Court of Appeals *instructed* the district court that it was improper to dismiss references on the basis that they were not from the field of pharmaceuticals. On the first appeal, the Court of Appeals held that the District Court should consider the McCutcheon's prior art reference despite the fact that "it did not describe the use of octoxynol 40 in pharmaceuticals and indicated that it had other uses" and held that "*McCutcheon's* 'cannot be so lightly overlooked.'" Pet. App. 88a.

B. The Court of Appeals Considered, and Adopted, Apotex's Argument that Prior Art References Should Be Considered Even if they Address a Different Problem than the Patent.

Second, Apotex made the same argument to the Court of Appeals in its motion to recall the mandate that it makes here – that the district court violated *KSR* by making factual findings that the asserted prior art references "do not discuss the *problem* allegedly solved by the '493 patent." Pet. 14-15, 17 (emphasis in original); *compare with* Res. App. 55a-56a. Apotex's argument – here and before the Court of Appeals – is that merely by making this accurate observation, the district court violated this Court's holding in *KSR* that courts should look beyond "those elements of prior art designed to solve the same problem." 127 S. Ct. at 1742.

In fact, the district court did not commit the error committed by the Federal Circuit in *KSR* because it did not restrict itself to considering prior art addressing the problem to be solved by the patented inventions. The district court considered all of the asserted prior art, even though none of it addressed the problem solved by the '493 patent. Pet. App. 15a ("[T]he Court will consider *all the references Defendants have cited.*") (emphasis added). That was, again, exactly what the Court of Appeals had directed it to do.

C. The Court of Appeals and the District Court Considered, and Had Already Agreed with, Apotex's Argument that a Motivation to Combine Need Not be Found Explicitly in the Prior Art.

Third, Apotex made the same argument in its motion to recall the mandate that it makes here – that the district court's opinion was inconsistent with *KSR* because it "made a rigid finding that the prior art references do not suggest substituting surfactants or the equivalency of O_{40} to other surfactants," rather than looking to "a multitude of sources" or "common sense." Pet 15-17; *compare with* Res. App 57a-58a.

Moreover, Apotex made this same argument to the *district court* on remand from the first appeal in this case. And in fact, the district court did not restrict itself to the prior art references themselves or require an "explicit" motivation to combine in analyzing obviousness. The district court considered the testimony of Apotex's expert presenting a rationale as to why the patented inventions would have been obvious to one of ordinary skill in the art, and every other piece of evidence and argument that Apotex offered in support of obviousness.

The district court rejected the opinions of Apotex's expert, Dr. Mitra, not out of a refusal to consider evidence other than the prior art patents and publications, but because "Dr. Mitra's opinions are based on tests that post-date the filing of the '493 patent applications; suffer from methodological flaws, and are directly contradicted by [Respondents' expert] Dr. Stella's testimony. Taken together, these factors undermine the validity of Dr. Mitra's opinions and compel the Court to find that his testimony is not credible." Pet. App. 41a. That the district court exercised its prerogative as the finder of fact to reject the

testimony of a witness it found not to be credible is not inconsistent with *KSR*. In particular, the district court did not refuse to consider "inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 127 S. Ct.. at 1741. The district court considered all of Apotex's evidence and arguments, but simply found them unconvincing.

Once again, the district court properly considered all of the evidence because on the first appeal in this case, the Court of Appeals instructed the district court that it should not require an explicit disclosure in the prior art references in analyzing obviousness. The Court of Appeals held:

> What a reference teaches or suggests must be examined in the context of the knowledge, skill, and reasoning ability of a skilled artisan. What a reference teaches a person of ordinary skill is not, as Syntex's expert appears to believe, limited to what a reference specifically "talks about" or what is specifically "mentioned" or "written" in that reference.

Pet. App. 86a-87a. Accordingly, it is specious for Apotex to argue here that the Court of Appeals has never had the opportunity to consider the argument that "[i]t is of no consequence that O_{40} was not mentioned in the prior art patents" or that "a motivation to combine need not be explicitly identified in the asserted references." Pet. 16. The Court of Appeals has not only considered these arguments, but adopted them in a published opinion in this case. And the district court did not make these errors on remand from the first appeal.

* * *

In short, there is no reason to GVR to allow the Court of Appeals "to consider potentially relevant decisions and

arguments that were not previously before it." *Stutson*, 516 U.S. at 197. The Court of Appeals had already adopted every one of the legal arguments Apotex presses here. And Apotex has already laid to rest any doubt about whether the Court of Appeals would reach a different conclusion in light of *KSR* by filing a motion that presented to the Court of Appeals every single argument it now presents to this Court.

D. The Court of Appeals Must Have Rejected Apotex's Arguments on the Merits to Deny its Motion to Recall the Mandate.

Not only did Apotex present all these arguments to the Court of Appeals, but the court must have rejected them on the merits. *KSR* was the sole basis Apotex presented for recalling the mandate, and Respondents opposed the motion on the merits.

This case is therefore unlike this Court's decision in *Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Company*, 520 U.S. 893 (1997). In *Lords Landing*, the Court held that, although the petitioner had presented intervening authority to the Court of Appeals in a motion to recall the mandate, it was unlikely the Court of Appeals had, in fact, considered that intervening authority in its summary denial of the motion. This was because "[i]n opposing petitioner's motion [to recall the mandate], respondent argued that a court of appeals lacks authority to recall its mandate, and the Court of Appeals may have rested its denial of petitioner's motion on this procedural ground." *Id.* at 897. Further, "the procedural ground [for denial] is by far the most likely. . . ." *Id.*

Here, unlike in *Lords Landing*, Respondents did not oppose Apotex's motion to recall the mandate with the argument that the Court of Appeals lacks authority to recall its mandate. Res. App. 43a-45a. Instead, Respondents

argued that the issuance of *KSR* did not present exceptional circumstances to justify recalling the mandate because the district court's opinion *already complied with KSR*. Res. Pet. at 6-11.[3] This was the only basis on which the Court of Appeals could have denied Apotex's motion. Accordingly, there can be no doubt but that the Court of Appeals considered the substantive question of whether the district court's opinion complied with *KSR*.

II. THERE IS NO REASONABLE PROBABILITY THAT THE DECISION BELOW RESTS UPON A PREMISE THAT THE COURT OF APPEALS WOULD REJECT IF GIVEN THE OPPORTUNITY FOR FURTHER CONSIDERATION.

GVR should be denied on the further, independent ground that there is no "reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration." *Lawrence*, 516 U.S. at 167. This is so for two reasons. First, the district court simply did not make the mistakes Apotex alleges it made, as pointed out above. *See* Section I, *supra*. Second, this appeal was briefed and argued in light of recent Federal Circuit precedent that is in harmony with *KSR*.

In *KSR*, this Court noted that "[i]n the years since the Court of Customs and Patent Appeals set forth the essence of

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[3] Respondents did raise a procedural argument in opposition to a *separate* motion—a motion for an extension of time to petition for rehearing. *See* Res. App. 34a-49a. Respondents argued that this motion should be denied because Apotex had waived its opportunity to petition for rehearing. Res. App. 40a-42a. But Respondents did not press any such ground as a basis for denying the motion to recall the mandate.

the TSM test, the Court of Appeals no doubt has applied the test in accord with [the principles laid out in *KSR*] in many cases." 127 S. Ct. at 1741. Indeed, after this Court granted certiorari in *KSR*, the Federal Circuit issued several panel decisions that applied a flexible approach to the obviousness inquiry that was fully consistent with *KSR*. The Court explicitly recognized in *KSR* that "the Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter." *Id.* at 1743 (citing *Alza Corp. v. Mylan Labs, Inc.*, 464 F.3d 1286 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (2006)).

These two opinions that the Court cited in *KSR* for "a broader conception of the TSM test" are fully consistent with *KSR*. Further, both opinions were fully briefed and argued to the Court of Appeals in this case. Thus, the Court of Appeals already applied the analysis of *KSR* in affirming the district court.

In *Alza Corp. v. Mylan Labs, Inc.*, 464 F.3d 1286 (Fed. Cir. 2006), the Federal Circuit held that "[t]here is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine the references." *Id.* at 1291 (emphasis in original). The Federal Circuit made clear that "the motivation to combine need not be found in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art." *Id.* (quoting *Cross Med. Prods., Inc. v. Medtronic Sofamar Danek, Inc.*, 424 F.3d. 1293, 1322 (Fed. Cir. 2005)). The *Alza* opinion was therefore consistent with this Court's instruction in *KSR* that the obviousness analysis not be "confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the

importance of published articles and the explicit content of issued patents." *KSR*, 127 S. Ct.. at 1741. The *Alza* opinion was also consistent with this Court's instruction in *KSR* that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

Similarly, in *Dystar* the Federal Circuit recognized that "[t]he conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference." 464 F.3d at 1366 (quoting *In re Lee*, 277 F.3d 1338, 1341 (Fed. Cir. 2002)). Consistent with this instruction, the *Dystar* court held:

> that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the "improvement" is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint or suggestion in the references themselves.

464 F.3d at 1368. The *Dystar* opinion is fully consistent with what this Court later held in *KSR*—that a court should look to multiple sources in considering whether a claimed invention would have been obvious, such as "design incentives and other market forces" and "any need or problem known in the field of endeavor at the time of

invention and addressed by the patent." 127 S. Ct. at 1740, 1742.

There is no reason to believe the Court of Appeals would find the district court's opinion inconsistent with *KSR* because the appeal below was briefed, argued, and decided based on the "broader conception of the TSM test" reflected in *Alza* and *Dystar,* not based on the rigid analysis that was rejected in *KSR*. *See* Appellees' Br. at 15, 26-27, 29; Appellants' Reply Br. at 7, 15 (citing *Alza* and *Dystar*.)

Moreover, at oral argument before the Court of Appeals, Apotex raised and argued another recently issued Federal Circuit opinion that is also fully consistent with *KSR*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007). Res. App. 3a. In *Pfizer*, the Federal Circuit properly recognized that the district court must consider prior art even if it does not address the same problem to be solved as the patent being challenged. 480 F.3d at 1363. This was in accordance with this Court's holding in *KSR* that it is error to assume "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." 127 S. Ct. at 1742.

In short, there is no reason to believe that the Court of Appeals would conclude on remand that the district court's opinion was inconsistent with *KSR*, because cases consistent with *KSR* were briefed and argued to the Court of Appeals, and the Court of Appeals affirmed in light of them.

III. A GVR HERE WILL NOT CHANGE THE ULTIMATE OUTCOME OF THE LITIGATION.

This Court should not GVR for the further, independent reason that Apotex cannot meet the third factor favoring a GVR. Even in the unlikely event that on remand from this Court, the Court of Appeals were to conclude that the district

court erred under *KSR* in its consideration of *prima facie* obviousness, "such a redetermination [would not] determine the ultimate outcome of the litigation." *Lawrence*, 516 U.S. at 167.[4] The judgment of infringement and the relief the district court granted under the Hatch Waxman Act would stand on two, separate, independent grounds, unaffected by this Court's opinion in *KSR*. First, a finding that the independent claims of the patent were invalid under *KSR* would not affect the district court's finding that Apotex has never offered any evidence that other claims of the '493 patent—the dependent claims—are invalid or not infringed. Second, it is in no way clear that reconsideration of the *prima facie* case under *KSR* would change the ultimate conclusion that the '493 patent is valid because the district court concluded that Apotex made a strong showing to overcome any *prima facie* showing of obviousness.

A. A Redetermination on Remand Would Not Affect the District Court's Opinion that the Dependent Claims of the '493 Patent are Valid and Infringed.

Congress has determined that "[e]ach claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of the other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282. Apotex's proposed product infringes each claim of the '493 patent. Pet. App. 7a, 120a. That means that, in order to sell its product, Apotex was

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[4] For its part, Apotex makes no showing on this third factor, merely stating without support that "[s]uch a redetermination may re-determine [sic] the ultimate outcome of the litigation." Pet. 25 (quoting *Lawrence*, 516 U.S. at 167).

required to prove that each and every claim of the '493 patent was invalid.

Apotex has never offered any evidence to demonstrate that certain claims of the '493 patent (the "dependent" claims 2-7, 9-14, and 16) are invalid. All that Apotex has ever offered is the bare assertion that these other claims are "substantially, materially identical" to the claims it did attempt to prove invalid. Pet. App. 65a-67a. The district court rejected this assertion, finding that the dependent claims "disclose more detailed inventions than the patent's independent claims, and that the elements claimed in the dependent claims have a major effect on the stability and antimicrobial effectiveness of the formulations." Pet. App. 66a. In other words, because the "dependent" claims of the patent disclose different inventions than the other claims, Apotex was required to adduce additional evidence to show that these claims were invalid. The district court concluded that "[b]ecause there was no evidence introduced that the more detailed inventions of the dependent claims of the '493 patent would have been obvious to a person of ordinary skill in the art at the time of their invention, the Court finds that the inventions of the dependent claims (Claims 2-7, 9-14, and 16) would not have been obvious to such a person." Pet. App. 66a-67a.

This Court's opinion in *KSR* can have no impact on this finding by the district court that the dependent claims are valid. *KSR* nowhere holds that an accused infringer can prove by clear and convincing evidence that a patent is invalid without adducing any evidence whatsoever. Indeed, Apotex does not even raise the issue of the dependent claims in its Petition for Certiorari.

Hence, even if the Court were to vacate and remand to the Court of Appeals, and the Court of Appeals (or the district court) were to conclude ultimately that the

independent claims are invalid under the *KSR* standard, the finding that the dependent claims are valid and infringed would stand. The relief granted by the district court – a permanent injunction and an order under the Hatch Waxman Act that the FDA not grant final approval to Apotex's ANDA – would also stand based on Apotex's infringement of the dependent claims.

Accordingly, this Court should not GVR because the issue to be reexamined could not "determine the ultimate outcome of the litigation." *Lawrence*, 516 U.S. at 167.

B. A Redetermination on Remand Would not Affect the District Court's Findings that There Was Strong Evidence to Overcome any *Prima Facie* Showing that the Patent was Invalid.

An evaluation of obviousness is a two-step analysis. *See Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.* 471 F.3d 1369, 1380 (Fed. Cir. 2006). The first step is an evaluation of whether the accused infringer has made out a *prima facie* case that the invention was obvious in light of the prior art. In the second step, the patent holder can overcome the *prima facie* case by pointing to "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966) (quoted in *KSR*, 127 S. Ct. at 1730). "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

KSR addressed the standard for determining whether an invention was obvious in light of the prior art. Even if the Court of Appeals were to conclude that *KSR* somehow affected the outcome of this first step, the result of this case

would remain the same. That is because the district court also found that there was "objective evidence [of secondary considerations] that strongly attests to the non-obviousness of the inventions of the '493 patent." Pet. App. 60a.

Specifically, the district court found:

- that "Plaintiffs have submitted copious evidence that their commercial embodiment of the patented inventions, ACULAR®, has had commercial success," Pet. App. 61a;

- that evidence of third-party licensing of the '493 patent was "highly probative" of its non-obviousness, Pet. App. 63a;

- that "[t]he fact that the inventions satisfied a long-felt need present at Syntex for a ketorolac-based ophthalmic drug also weighs strongly in favor of a finding of non-obviousness," Pet. App. 64a; and

- that "the patented inventions produced unexpected results," Pet. App. 34a.

These factual findings are not at issue in Apotex's Petition and there is nothing in *KSR* that would cause the lower courts to disturb these factual findings. The strong evidence of these "secondary considerations" makes it improbable that the ultimate outcome of this litigation would be different, even if the Court of Appeals ultimately concluded that the district court's consideration of *prima facie* obviousness was inconsistent with *KSR*.

IV. THE EQUITIES OF THE CASE COUNSEL AGAINST A GVR.

Finally, the equities of this case counsel strongly against a GVR. Where, as here, "the delay and further cost entailed in a remand are not justified by the potential benefits of further consideration by the lower court, a GVR order is inappropriate." *Lawrence,* 516 U.S. at 167-68.

This case has been in litigation for five years. In those five years, Syntex and Allergan have expended tremendous resources, including litigating a three-week trial, a first appeal, a hearing and briefing on remand on the question of whether Apotex has adduced clear and convincing evidence that the '493 patent is invalid, and a second appeal. In all these proceedings, Apotex has never been able to convince any court that the '493 patent is invalid. To vacate the judgment of the Court of Appeals here would needlessly force Syntex and Allergan to expend further resources defending the patent, even though, for the reasons detailed above, it is highly unlikely that such further proceedings will affect the outcome of this litigation.

CONCLUSION

The Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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August 9, 2007

APPENDIX

The following is a transcript of the audio recording of the oral argument held on April 5, 2007 before the U.S. Court of Appeals for the Federal Circuit in this case. The transcript was prepared by a certified court reporter. Respondents provided Petitioners the opportunity to identify errors in the transcription but Petitioners declined.

[1] UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Plaintiffs-Appellees,

v. Case No. 06-1495

APOTEX, INC., APOTEX CORP., and

NOVEX PHARMA

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN C01-02214 MJJ,

JUDGE MARTIN J. JENKINS

Reporter's Transcript of

Audio Recording Transcription

Transcribed By: Keri Veare, CSR 11220, RPR (1-398623)

[2] TRANSCRIPTION

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MR. SILVER: Thank you, your Honor. The '493 patent-in-suit is Syntex's third patent in a series of a lawfully extended patent monopoly. Its first patent covered KT, ketorolac tromethamine, the active ingredient. The second patent, the Waterbury patent, covered KT in an ophthalmic formulation. The third patent before us is an alleged improvement patent but is invalid for obviousness.

This Court stated in its 2005 opinion that the district court had committed at least five clear errors, one being that the unvarnished view of the prosecution history shows some weakness in the conclusion that the patentee established unexpected results for the claimed surfactant. Despite these clear five errors, the district court did not change a single ruling.

JUDGE 2: But you went back to the district court and the road map, at least, was established by the last opinion in this Court, even though it was not followed?

MR. SILVER: Absolutely, your Honor.

JUDGE 2: Is that what you're saying?

MR. SILVER: Yes, your Honor.

JUDGE 2: Is there additional evidence that

[3]

was submitted?

MR. SILVER: No, your Honor. It was merely attorney argument at that point.

JUDGE 2: So it's only attorney argument plus reweighing of the evidence?

MR. SILVER: Correct.

JUDGE 2: And you're asking us to reweigh again?

MR. SILVER: Unfortunately, yes. We're back here for now the fifth time. In addition to the remand, this Court has vacated three interlocutory -- we had to come here three times to have vacated the judge's TRO and preliminary injunction, so that we're now back here for the fifth time.

JUDGE 2: I think the Court's pretty familiar with the procedure in this case. It's been around a few years and few opinions have been issued regarding the orders. But what I'm still concerned about, you want us to reweigh the evidence on behalf of the lower court? The same evidence that was there before, you want us to reweigh it. I mean, that's not our function.

MR. SILVER: No. What I believe the Court should do is find the clear errors that the district court made, yet again. They were pointed out to the district court in this Court's last opinion, and despite

[4]

the road map that the Court gave them, the court still chose to make clear errors in its finding. And I'd like to go through them just to point out the continuing clear error that the district court made when it was asked to reweigh and relook at the evidence in light of this Court's direction.

I'd also like to point out to the Court an opinion that issued two weeks ago, the Pfizer versus Apotex case, March 22, 2007, appeal 2006-1261, where the Court held that claims covering a specific pharmaceutically acceptable salt were obvious over the prior art, and there were no unexpected results.

As we know, the '493 patent inventor Lidgate submitted her declaration to the PTO attempting to find and show unexpected results. But for that declaration, the '493 patent would not have issued.

This Court found as a fact that the pharmaceutical expert report 303 established an important fact that

Octoxynol 40 was a well-known ingredient in pharmaceutical products at the time of the invention.

The district court clearly erred when it mischaracterized the Court's remand order and incorrectly found that Octoxynol 40 may have been used in one or more unknown pharmaceutical products, and gave

[5]

it only limited weight.

Now, when we look at the Lidgate declaration for unexpected results, there are four important factors: What it included, what is omitted, and when and how she tested the Octoxynols.

JUDGE 1: Was there anything in the record other than one passing statement in a report that O-40 was well known in the art?

MR. SILVER: Actually, Syntex cited --

JUDGE 1: And that was, of course, with reference to cosmetics in one of the pharmaceuticals.

MR. SILVER: Well, actually, 303 said pharmaceuticals. It did not say cosmetics.

JUDGE 1: And then the expert witnesses when -- your expert witness, when asked, said, "Well, no, he doesn't know of anything, except maybe cosmetics."

MR. SILVER: Correct.

JUDGE 1: That's your witness?

MR. SILVER: That was my witness. He said that it had been well known for uses as a surfactant and had been used in cosmetics.

JUDGE 1: Not in pharmaceuticals?

MR. SILVER: Not to his knowledge, but if you look at the file --

[6]

JUDGE 1: That's your witness?

MR. SILVER: Yes, your Honor.

JUDGE 1: Now, if we're reweighing the evidence, you just lost, didn't you?

MR. SILVER: No, your Honor, because when you look at the file history, there are three pieces of prior art that showed Octoxynol 40 was well known in the art.

When we look at the '493 patent and the unexpected results, it showed that the solutions were to remain clear over time. That's shown in column 8 of the patent.

When Lidgate tested the 12.5 and the Octoxynol 40, she found a look equivalent, a visual comparison. She made no other finding. The day she tested the Octoxynol 3, the 12.5, and the O-40, she didn't even prepare the Octoxynol 5. She did that three months later. She only did that when she discovered that 12.5 and O-40 look equivalent.

So she knew she had two out of the three look equivalent, so she immediately prepared the Octoxynol 5. She knew when she prepared those solutions that they would fail.

She knew Octoxynol 3 and Octoxynol 5 were not soluble in water. They were turbid when she took them

[7]

out of the bottle. She expected that they would fail in the test that she submitted; therefore, she didn't even have to put them on stability. There is nothing unexpected about that result.

She testified, as Dr. Mitra testified, that they're water insoluble and that they are turbid, and there's no unexpected results. Dr. Mitra testified that no one in their right mind would compare two water-insoluble surfactants and a water-soluble surfactant, namely Octoxynol 40.

Dr. Freyberg, who prosecuted the '493 patent, also knew that Octoxynol 3 and Octoxynol 5 were water insoluble. The literature showed --

JUDGE 2: Because they were oil based?

MR. SILVER: They were oil based. And, as Dr. Mitra testified, the ethylinoxide chains were too short to be able to form micelles.

And Dr. Stella even testified that you know you have to be able to form micelles and you have to be above the CMC, critical micelle concentration level, in order to solubilize a KT BAC interaction.

No one has ever explained to this day why the Octoxynol 3 data is in that Lidgate declaration. Dr. Freyberg said he left out the 12.5 data because it wasn't in the prior art and it wasn't part of the claimed

[8]

invention.

Well, neither is Octoxynol 3. There was no justification for putting in two water-insoluble surfactants when comparing it to the water soluble. We submit had the 12.5 data been included in the Lidgate declaration, it would not have shown unexpected results.

JUDGE 1: You're asking us to reweigh the evidence. Let me switch our focus a little bit. You challenge the permanent injunction here. Given that Hatch Waxman is an artificial infringement case in the first place and the statute says that on the ruling against you there shall be nothing that issues, why isn't that tantamount to a permanent injunction?

MR. SILVER: Because we submit that the court still must go through the factual analysis, and we came back --

JUDGE 1: You lose. There's a patent in place. The Hatch Waxman Act has given you a free shot without infringing at proving your case and you failed, and the statute says now, since you failed, FDA will not issue any certification for you to proceed to market; and, yet, you say, No, we should still be allowed to proceed to market?

MR. SILVER: No. I'm saying that the court should have at least made the analysis that would have

[9]

allowed us --

JUDGE 1: We're working on a legal argument here, not a procedural one. I'm wondering on the law where is your argument that there needs to be any analysis given that -- the context of a Hatch Waxman situation?

MR. SILVER: Well, your Honor, neither side has cited any case specifically on point.

JUDGE 1: No, of course. There's nothing there.

MR. SILVER: This is the first time.

JUDGE 3: In the language of the statute, it says the court shall order. I mean, the eBay analysis was in an injunction context predicated on some modicum of discretion by the trial court, and just -- as Judge Rader mentioned, where's the discretion in 27184(a), which says the court shall? Where's the discretion there?

MR. SILVER: Well, our point, your Honor, is that the court should engage in the analysis, so that if one of the four factors is an overriding factor, for example, the public interest factor, it could still find that an injunction due to public interest could not --

JUDGE 1: So, in other words, a generic would always get to -- on the market as long as it was an important health-saving drug, right?

[10]

MR. SILVER: No.

JUDGE 1: Because they would argue public interest. Again, it's an infringement, but we're allowed to go on the marketplace because this is an -- important for public safety.

MR. SILVER: Not -- in every instance, if it were an extreme emergency --

JUDGE 1: In any instance, where is the discretion, as Judge Prost was pointing out to you, to even reach that point?

MR. SILVER: Well, your Honor, we submit that the district court still must engage --

JUDGE 1: Just because you're an important drug, you can ignore the rights of the party that developed that drug that cost billions of dollars; is that what you're saying? I invent the cure for AIDS. Because I've invented the cure for AIDS, you get to put it on the marketplace as a generic, undercutting my billions of dollars of investment just because it's a cure for AIDS; is that your argument?

MR. SILVER: No, your Honor. But if the court --

JUDGE 1: Tell me why that isn't your argument.

MR. SILVER: Your Honor, what we're saying is

[11]

that the court must have engaged in the analysis, because --

JUDGE 1: That's procedural. We're talking about the law here. Help me with the law. Why isn't that your legal argument? That's what you want, right?

MR. SILVER: Yes, your Honor. If there's an overriding --

JUDGE 1: Thank you. At least we got to that point. But where in the statute are you given any right to make that argument?

MR. SILVER: The statute does say "shall," so it does not --

JUDGE 1: Give you the right to make that argument.

MR. SILVER: Yes, your Honor.

JUDGE 3: And so you want the right to go back and argue over the permanent injunction, but assuming, hypothetically, you would affirm the district court on the findings with respect to obviousness, it would need the 271 order in place, so why does it matter whether you get the injunction if you're still left with not being able to get FDA approval in any event?

MR. SILVER: That is certainly a practical aspect of it, your Honor.

JUDGE 2: But you couldn't produce if the FDA

[12]

approved.

MR. SILVER: No, because in this particular case, there was only tentative approval. There was not any final approval issued by the time of the litigation decision.

JUDGE 2: That was subject to the certification?

MR. SILVER: Yes, your Honor.

JUDGE 2: So if you don't have the approval, then you can't produce with or without the injunction.

MR. SILVER: Correct.

JUDGE 2: So why would you need the injunction?

MR. SILVER: It was more a matter of showing the district court's failure to properly analyze as it had done in so many instances in this case. This Court has vacated its prior opinions on injunctions no less than three times, and here it didn't engage in a single analytical point on the injunction at all.

JUDGE 2: But that was still dependent upon the outcome of the obviousness analysis on remand.

MR. SILVER: Yes, your Honor.

JUDGE 2: So the injunction at that point is probably premature, isn't it, on the part of the court, to not having any kind of analysis at that point?

[13]

I think the rationale for the Court to dissolve the injunction was based upon the inability to determine how and why it was issued. There's no rationale behind it. So why is it now there is a rationale, basically a finding of validity?

At least as far as the statute is concerned, we couldn't issue the FDA approval with or without the injunction, period. I don't even know why they need the injunction.

MR. SILVER: That is correct.

As Ms. Lidgate testified at trial, going back to the unexpected results, she testified that it showed, in column 4 of the patent, any of the many surfactants listed in column 4 of the patent would have been useful in her alleged invention.

In addition, the file history showed that any non-ionic surfactant in an ophthalmic in a stabilizing amount was within the scope of the invention. That's Exhibit 24, JA10, 45 and 46.

These are clear admissions that virtually any water-soluble, non-ionic surfactant is suitable in the claimed invention. District Court clearly erred when it held there were no test results at the time of the invention that showed that other surfactants would work equally well compared to Octoxynol 40.

[14]

JUDGE 1: You're reading your rebuttal. You want to --

MR. SILVER: I'll stop right now, your Honor. JUDGE 1: All right. Thanks a lot, Mr. Silver. We'll hear from Mr. Brainerd.

MR. BRAINERD: Thank you, your Honor. Good afternoon. May it please the Court, it goes without saying that Apotex has a very heavy burden of proof by clear and convincing evidence that the '493 patent is obvious. They've had two bites at the apple, a three-week trial, and an extensive remand hearing before Judge Jenkins, and they haven't come close either time. And I think that the thrust of their arguments in their briefs, and to some extent here today, is to try to deflect our attention away from that fact by taking attacks at Judge Jenkins.

JUDGE 2: But, Mr. Brainerd, when that remand order was issued, as a matter of fact, and the reweighing of the evidence took place, it seems that they came up with the same results as before without too much reweighing of the evidence.

MR. BRAINERD: Well, I respectfully disagree, your Honor. I think if one were to look at the extensive findings of fact and conclusions of law that Judge Jenkins went through, he carefully reviewed all of

[15]

the evidence pursuant to your instructions. I'm happy to review any of that with you. For example, he went back and looked through each piece of prior art, specifically having in mind and reciting the fact that you had instructed him that he should never look at those pieces of art as teaching away. And so he did that, extensively. And he went through each piece of prior art -- that would be the Waterbury, Han, and Gilbert references, along with McCutcheon -- and carefully articulated what was missing from those pieces of prior art, and then, in further discussion, gave his opinion, after weighing all of the evidence, why none of that art would provide a motivation to combine and why it certainly wouldn't teach the invention of the '493 patent, so I think in that regard he did that.

And I'm happy to discuss any of that art and explain to you why Judge Jenkins reached that conclusion and why it's the right conclusion.

He was criticized for not going back and looking at the Syntex report, or whatever you want to call it, the Lidgate 2 report. He did that. He did that very carefully.

Now, he weighed that evidence. That's what a trial judge is supposed to do. He's supposed to weigh the evidence. If you look at that report, and the

[16]

testimony from Fu and Lidgate was, we don't recall what pharmaceutical we had in mind at the time we made that statement in that report.

So the status of the record in front of Judge Jenkins, as he took a look at that report pursuant to your instructions, was, Yes, Octoxynol 40 may have been used in one or more pharmaceutical applications. We don't know. What kind of application? We don't know what Octoxynol 40 was used for, whether it was ever used in ophthalmic application, whether it was ever used in an ophthalmic application in a

safe manner, whether it was ever used to resolve the complexation or incompatibility between a carboxyl group NSAID and a quaternary preservative. He had none of that.

And then he compares that to the testimony of their own witness, Dr. Mitra, who testified, rather uncategorically, that based upon his knowledge, and this is a man of skill in the science who presumably had gone through during this trial and looked very hard to find one, he did not know of any prior use or existing use of Octoxynol 40 in any pharmaceutical other than ACULAR®.

JUDGE 1: Mr. Brainerd, I'm going to shift gears on you, too.

MR. BRAINERD: Sure.

JUDGE 1: Let's go to the -- oh, excuse me, my

[17]

colleague has a question.

JUDGE 2: With respect to the lower court's determination on page 21, which is JA88 of the joint appendix, the lower court speaks to Dr. Mitra's critique of Syntex's relating -- testing relating to turbidity and was also unpersuasive.

Dr. Mitra's analysis of these -- there's a statement in the records showing that Dr. Mitra's analysis showed, "My studies also show, however, that several surfactants, including Octoxynol 30, Octoxynol 10 show greater turbidity than Octoxynol 40. Basically, relating all the water-soluble Octoxynols." Why is that not persuasive?

MR. BRAINERD: Well, as I think Judge Jenkins properly found, those tests were conducted in the year 2002; and, therefore, as a matter of evidence, they're irrelevant to demonstrate what one would have known of ordinary skill in the art --

JUDGE 2: I understand that they're not relevant. You said they were not persuasive.

MR. BRAINERD: Right. And he also found to be not credible, and that was another finding he made, as well.

In addition to that, he found them not credible, in part, for that reason. He found them not

[18]

credible, in part, because he found that they were scientifically flawed, because those tests did not look at and evaluate the variables that existed in this formulation.

For example, Mitra's tests only tested one batch of BAC, and there was extensive testimony in the record about BAC having different homologs, and the difference in those homologs would have a dramatic effect upon solubility. In addition to which, he had testimony from Dr. Stella, No. 1, which Dr. Mitra's entire scientific premise behind those tests was flawed. He had specific testimony, which is at 2080 from Dr. Stella who had --

JUDGE 1: Were these exactly the Stella experiments replicated?

MR. BRAINERD: No.

JUDGE 1: No, they weren't.

MR. BRAINERD: Stella did some work, You Honor, but this is Stella's testimony, looking at Mitra's analysis.

Mitra's analysis was based upon a theory about how BAC and ketorolac interact and how they fall out of solution and come back into solution.

And I don't know if the Court wants me to go through the entire theory, but what Dr. Stella did is he

[19]

looked at that theory or that analysis and said it's fatally flawed. The big flaw was because the more ketorolac tromethamine you put in the solution, the more ketorolac, the more K you put in, which undermines the entire analysis, so he found the analysis to be flawed for that purpose.

JUDGE 2: Fundamentally unsound.

MR. BRAINERD: Fundamentally unsound. Thank you, your Honor.

In addition to which, Dr. Stella at JA2080 specifically testified that "Non-ionic surfactants have different chemical structures; therefore, it performed differently, in part, because they have different critical micelle concentrations."

And Dr. -- and Judge Jenkins looked at that. He also looked at the fact, which is, I think, very compelling here, that the Syntex scientists who were testing back in the '82/'83 period, extensively tested a wide range of surfactants and found that there was a diversity in how they performed, and the ultimate resolution there was that Octoxynol performed better than every other one based upon extensive testing.

JUDGE 1: I'm going to shift the gears now.

MR. BRAINERD: Okay.

JUDGE 1: If you don't mind, Mr. Brainerd.

[20]

Despite my banter with Mr. Silver, it does appear to me that there might be a reason to have an injunction even after a finding that they can't go on the marketplace until the patent expires.

They could, with an injunction properly denied, make a stockpile of the drugs that could be available for marketing the very instant that the patent does expire, thus speeding the generic to the marketplace.

Why isn't that an appropriate reason and why doesn't that suggest that there ought to be some consideration of injunction post a finding of no infringement -- of infringement and invalidity?

MR. BRAINERD: Well, sir, Your Honor, you've just come up with a very, I suppose for want of a better word, creative observation.

All I can say is that under the construct of the Hatch Waxman Act, and you've already gone through this. I don't want to kind of repeat your arguments. But it's clear that Congress has set up a structure here which says if you've got a generic that's been found to be infringing of a patent, and that patent is either -- is valid and not expired, the whole thrust of the Hatch Waxman Act is to prevent you from going to market with that.

[21]

JUDGE 1: Granted.

MR. BRAINERD: Right. So I suppose --

JUDGE 1: We've already established if you go to market. The question is, do you get to further go on to the question of an injunction for the purpose of stockpiling it?

MR. BRAINERD: Certainly it's not contemplated by the Hatch Waxman Act, so I would say no.

JUDGE 1: Why isn't it? Because the Hatch Waxman Act does leave in place the prospect of injunction.

MR. BRAINERD: Well, because -- I may be wrong on this, your Honor, but I'm just going to throw out the only reason I can think of right now, which is, as your Honor

indicated a little while ago, there's a specific provision in the Hatch Waxman Act that says the judge shall issue an order.

JUDGE 1: I'm not going to argue that it was an artificial infringement case in the first place.

MR. BRAINERD: But what prevents the FDA from granting approval? I don't know whether they can make anything before they get an approval. I don't know the answer to that. I have to confess, I don't know the answer. But if, in fact, that's the case, that would be an adequate reason why even, you know, under an

[22]

injunction you shouldn't be allowed to start stockpiling six months ahead of time.

JUDGE 2: Wouldn't you need an injunction at that point, though, if they can't produce, because they need FDA approval at that point?

MR. BRAINERD: Well, arguably, the instruction -- the injunction under the circumstances would be sort of a belt-and-suspenders operation, because of a clear statutory mandate of (E)4(a), which is the statutory provision we're talking about here, clearly.

So other than that, your Honor, I can't -- I can't give you any further answer to your question. I just think that when you look at this construct as a whole, which clearly says you can't go to market, you can't get FDA approval under these circumstances, I don't think there would be any real basis coming back in front of a judge under an injunctive situation and asking permission to start stockpiling before you get approval from the FDA.

JUDGE 3: Well, wait. So are you saying that if we were to vacate, because we just don't know what to do with eBay, and vacate and remand to the district court judge to apply eBay, that you all wouldn't pursue your injunction in any event if indeed we otherwise left

[23]

the order, the Hatch Waxman order in place?

MR. BRAINERD: Well, I think we would pursue the injunction, because I think the injunction is coextensive of the whole thrust of the Hatch Waxman Act.

JUDGE 2: What would you need the injunction for?

MR. BRAINERD: Well, I guess to some extent the belt and suspenders, but I mean, to be absolutely sure that there's no wiggle room for these folks as to whether they can go out and do something that would be contrary to the thrust of the statute.

JUDGE 3: So if you're saying you would pursue an injunction even with this order in place, then why aren't -- is it incumbent upon us to send it back to the trial court to effectively analyze the factors under eBay?

MR. BRAINERD: Because, I believe, your Honor, that, as I said at the outset, and really the primary underlying reason here is, we're not operating under 283. We're operating under the Hatch Waxman Act. And the Hatch Waxman Act clearly creates this construct where I think we can all agree that Congress has intended us to do exactly what it said it was going to do, because Congress is -- in essence, saw or sensed irreparable harm if the contrary were allowed to happen.

[24]

JUDGE 2: Well, it doesn't speak to irreparable harm.

MR. BRAINERD: Well, the statute doesn't speak to irreparable harm. My point, your Honor, is when you look at the statutory construct as a whole, starting with the 30-day stay -- I mean, a 30-month stay and allow this matter to be litigated in the first place, Congress is very, very intent upon preventing anything that could happen to let a generic go to

market in a situation where it would be infringing a valid patent that had not yet expired.

JUDGE 2: You could also argue that the Hatch Waxman Act had the purpose of at least increasing competition in some of these areas by allowing generics to expedite their trip to the marketplace, except obviously under certification of part 4.

MR. BRAINERD: And which, of course -- I mean, I don't mean to be facetious, but that's where we are --

JUDGE 2: I understand.

MR. BRAINERD: -- that's the ballpark -

JUDGE 2: I understand.

MR. BRAINERD: -- we're operating here.

JUDGE 2: You still have some time left on the patent unless we reverse the district court's decision

[25]

on this point. At that point, assuming that we affirm, then the issue of whether or not an injunction would be required under the statute is questionable, but obviously, if it is still available, then maybe we should send it back and let the judge decide whether or not under eBay requirements an injunction is proper.

MR. BRAINERD: Well, to the extent there's any question in the Court's mind as to whether or not the judge should have issued the injunction, or whether he did so properly, I would suggest it's harmless error for the reasons we already talked about.

We have other issues in the brief as to whether they could have timely raised this in giving Judge Jenkins the opportunity to address these issues before the Court.

Our position is that he could. The opinion came out on the 15th of May. Judge Jenkins didn't even issue his order, final order in this case and the injunction until the 2nd of June, and the final judgment in this case wasn't entered until the 18th of August.

So there was ample opportunity -- and I think he should have had the opportunity to confront this initially. There was ample opportunity for them to bring this matter to the attention of the judge and the motion to reconsider or some kind of a letter brief, or

[26]

what have you, and they made no effort to do so, so I think there's a waiver.

JUDGE 1: Well, eBay happened in between.

MR. BRAINERD: Ebay happened on the 15th -- eBay happened after the hearing, no question about it. I think the hearing was on -- I haven't got that date, but it was in February. And the eBay opinion, in my recollection, came out on the 15th of May. Judge Jenkins issued the findings of fact in the order, which we have in front of us today, including the injunctive relief, on the 2nd of June. But a final judgment in this case was not entered until the 18th of August, is my point.

JUDGE 3: Has our Court dealt with that? I know we've got a few opinions, post eBay where we remanded, we sent it back because of eBay; do you know if any question dealt with a waiver argument on the timetable and the timing; do you know? I don't know.

MR. BRAINERD: My legal team kindly says no, so I'm going to say no, your Honor.

JUDGE 1: That's why you have a team. Thank you, Mr. Brainerd.

MR. BRAINERD: Absolutely. Thank you very much.

JUDGE 1: Mr. Silver, does anyone want to

[27]

comment on my attempt to pull your fat out of the fire?

MR. SILVER: No, your Honor, I think I'll leave it where it stands.

I do want to point out that Dr. Stella, their expert, did not perform a single test in this case. Dr. Mitra performed tests for two years. His tests confirmed what Syntex found and what Novex Pharma found.

When the district court found his tests to be flawed because he didn't test different grades of BAC and different lots of KT, there's nothing in the '493 patent that requires that. And, in fact, if you look at column 3, it says, "The ingredients used in the formulation of the present invention are typically commercially available or can be made by methods readily known to those skilled in the art."

Dr. Mitra tested KT. He tested two other NSAIDs. He tested three of the preservatives, cetrimide, CPC, and BAC. Lidgate testified she only ever tested BAC and she only ever tested ketorolac tromethamine.

So Dr. Mitra's tests far surpassed what anyone at Syntex ever did, and Dr. Mitra obtained his ingredients from commercial sources, including those from Novex Pharma. And I see at this point I'm out of

[28]

time.

JUDGE 1: Thank you very much, MR. SILVER.

(End of audio.)

[29]

REPORTER'S CERTIFICATE OF TRANSCRIPTION

I, Keri J. Veare, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing audio recording transcription was transcribed by me to the best of my ability and knowledge;

That the foregoing is a true and correct transcription of my shorthand notes of the requested audio recording transcription transcribed by me;

WITNESS my hand and seal this 31st day of July 2007.

/s/ Keri J. Veare
KERI J. VEARE, CSR 11220

Appeal No. 2006-1495

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC., APOTEX CORP., and NOVEX PHARMA

Defendants-Appellants.

DEFENDANTS-APPELLANTS' MOTION TO RECALL AND STAY THE MANDATE

Appeal from the United States District Court for the
Northern District of California
The Honorable Judge Martin J. Jenkins
District Court Case No. CV-01-2214 MJJ

Robert S. Silver, Manny D. Pokotilow, Mona Gupta, William J. Castillo
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Attorneys for Defendants-Appellants
Apotex, Inc., Apotex Corp. and Novex Pharma

May 3, 2007

[CERTIFICATE OF INTEREST OMITTED]

Appellants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby move the Court to recall and stay the mandate it issued on April 30, 2007, until it has rendered a decision on Apotex' accompanying Petition for Rehearing and Rehearing *En Banc*. Apotex is contemporaneously filing, with this Motion, a Combined Petition for Panel Rehearing and Rehearing *En Banc* ("Rehearing_ Petition") and a Motion for Extension of Time to file the Rehearing Petition as well as the present Motion ("Motion for Extension of Time"), and supporting Declaration of Robert S. Silver. Apotex has informed Syntex through its counsel, Mr. Alexander Brainerd, that Apotex will seek an extension of time to file the Rehearing Petition. (Exh. A). Mr. Brainerd, in turn, has informed counsel for Apotex that Syntex objects to, and will oppose such an extension of time. (Exh. A).

The same day that this Court issued its mandate (April 30, 2007), the United States Supreme Court rendered its decision in *KSR Int'I Co. v. Teleflex Inc.*, 550 U.S. ____, 2007 WL 1237837 (U.S. Apr. 30, 2007). As explained in detail in Apotex' Rehearing Petition, *KSR* has significantly relaxed the application of the teaching, suggestion, motivation (TSM) test in the obviousness inquiry. The district court, as affirmed by a panel of this Court, had applied the TSM test, in a manner incompatible with the Supreme Court's holding in *KSR*. In short, for this, as well as other reasons, it is highly likely that should rehearing be granted, this Court's mandate would be reversed.

In *U.S. v. Kismetoglu*, 476 F.2d 269 (9th Cir. 1973), the Ninth Circuit granted an appellant's motion to file a petition for rehearing and recall its mandate, due to a United States Supreme Court decision which changed controlling precedent. In *Kismetoglu*, the Supreme Court's decision issued 42 days after the Ninth Circuit had issued its original opinion, yet the Ninth Circuit recalled the mandate in view

of the Supreme Court's decision. In this case, only half that time had passed, as compared with Kismetoglu, between the panel's decision and the Supreme Court's decision in *KSR*.

In view of the intervening sweeping change in the law of obviousness and the need to apply the law with consistency and uniformity, Apotex respectfully requests this Court to recall and stay its mandate until a decision is reached on rehearing.

Respectfully submitted

May 3, 2006

By /s/ Robert S. Silver

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Gornish, David

From: Brainerd, Alexander L. [alexandertrainerd@hellerehrman.com]

Sent: Tuesday, May 01, 2007 5:28 PM

To: Gupta, Mona

Subject: RE: Syntex v. Apotex appeal

Given that the mandate has issued, I do not know on what basis you could seek an extension of time. In any event, we do object and will file an opposition

---

From: Gupta, Mona [mailto:monagupta@abcp.com]

Sent: Tuesday, May 01, 2007 11:49 AM

To: Brainerd, Alexander L.

Cc: Silver, Robert S.

Subject: Syntex v. Apotex appeal

Dear Mr. Brainerd - Pursuant to Fed.Cir.R. 26(b)(2), we are providing you with notice that we will be seeking an extension of time to file a Combined Petition for Panel Rehearing and Rehearing En Banc in view of the Supreme Court's recent decision in KSR v. Teleflex. Please advise if you have any objection and, if so, whether Syntex will file an opposition. I look forward to an early response to this e-mail.

Thanks,
Mona

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Appeal No. 2006-1495

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC., APOTEX CORP., and NOVEX PHARMA

Defendants-Appellants.

DEFENDANTS-APPELLANTS' MOTION FOR EXTENSION OF TIME TO FILE COMBINED PETITION FOR PANEL HEARING AND REHEARING *EN BANC* AND MOTION TO RECALL AND STAY MANDATE

Appeal from the United States District Court for the
Northern District of California
The Honorable Judge Martin J. Jenkins
District Court Case No. CV-01-2214 MJJ

Robert S. Silver, Manny D. Pokotilow, Mona Gupta, William J. Castillo
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Attorneys for Defendants-Appellants
Apotex, Inc., Apotex Corp. and Novex Pharma

May 3, 2007

[CERTIFICATE OF INTEREST OMITTED]

Appellants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby move the Court for an extension of time pursuant to Fed.Cir.R. 26(b)(1)(B) to file its Combined Petition for Panel Rehearing and Rehearing En Banc ("Rehearing Petition") and its Motion to Recall and Stay the Mandate ("Recall Motion"). The Rehearing Petition and the Recall Motion are being contemporaneously filed with the present Motion. Apotex respectfully requests that a briefing schedule be set so the parties can address the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. , 2007 WL 1237837 (U.S. Apr. 30, 2007), and its applicability to the present case.

Fed.Cir.R. 35(c) gives the petitioner 14 days from the entry of judgment to petition for rehearing. The Rehearing Petition is untimely because the panel entered its judgment affirming the district court on April 9, 2007. The 14 day deadline would have given Apotex until April 23, 2007 to petition for rehearing. However, the United States Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S., 2007 WL 1237837 (US. Apr. 30, 2007) has given rise to extraordinary circumstances warranting an extension of time to file the Rehearing Petition pursuant to Fed.Cir.R. 26(b)(1)(B).[1] These extraordinary circumstances are described in detail in the accompanying Declaration of Robert S. Silver in Support of the present Motion as well as in the Rehearing Petition.

Pursuant to Fed.Cir.R. 26(b)(2). Apotex has informed Syntex through its counsel, Mr. Alexander Brainerd, that Apotex will seek an extension of time to file the Rehearing Petition. (Exh. A). Mr. Brainerd, in turn, has informed counsel for Apotex that Syntex objects to, and will oppose

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[1] The Court issued its mandate the same day that the Supreme Court issued *KSR*, April 30, 2007.

such an extension of time.[2] (Exh. A).

Pursuant to Fed.Cir.R. 26(b)(4)(A), the date to be extended is April 23, 2007. Pursuant to Fed.Cir.R. 26(b)(4)(B), the revised date sought is May 7, 2007. Pursuant to Fed.Cir.R. 26(b)(4)(C) the number of days of extension sought is 14 days. Under Fed.Cir.R. 26(b)(4)(D) no extensions have previously been granted to Apotex.

As explained in greater detail in the Rehearing Petition, *KSR* is highly likely to result in a reversal of the district court's finding of nonobviousness of the patent-in-suit. Given that *KSR* was issued only one week after the deadline for the timely filing of a petition for rehearing and that *KSR* is highly likely to effect the outcome of the case, Apotex respectfully requests the Court to grant an extension of time such that the contemporaneously filed Rehearing Petition is deemed timely.

Additionally, Apotex respectfully requests the Court to set a briefing schedule so that the parties can address the obviousness issues with respect to the guidelines set forth by the Supreme Court.

Respectfully submitted,

May 3, 2006

By /s/ Robert S. Silver
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[2] This statement satisfies the requirement set forth in Fed.Cir.R. 26(b)(3).

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Thanks,
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[PROOF OF SERVICE OMITTED]

2006-1495

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC., APOTEX CORP., and NOVEX PHARMA

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN C01-02214 MJJ, JUDGE MARTIN J. JENKINS

APPELLEES' OPPOSITION TO APPELLANTS' MOTION TO RECALL AND STAY THE MANDATE, AND FOR EXTENSION OF TIME TO PETITION FOR REHEARING

Appeal from the United States District Court for the Northern District of California
The Honorable Judge Martin J. Jenkins
District Court Case No. CV-01-2214 MJJ

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May 7, 2007

[CERTIFICATE OF INTEREST OMITTED]

TABLE OF CONTENTS

Page No.

INTRODUCTION 1

BACKGROUND 2

ARGUMENT 3

I. Apotex Has Waived Its Oportunity to Petition for Rehearing or for an Extension of Time. 3

II. As a Rule 36 Summary Affirmance, This Appeal Is an Especially Poor Candidate for Recall of Mandate and Rehearing. 5

III. The Supreme Court's KSR Decision Is Not an "Extraordinary Circumstance" Sufficient to Provoke Recall of the Mandate in this Case 6

A. Legal Standard 6

B. This Court's Summary Affirmance of the District Court's Order Is Consistent with KSR 8

1. KSR affirmed that unexpected results may render combination patents nonobvious. 9

2. Legal Reasoning in KSR cannot render Apotex's expert's opinion credible. 11

CONCLUSION 12

TABLE OF AUTHORITIES

Page No.

CASES

Alza Corp. v. Mylan Labs., Inc.,
464 F.3d 1286 (Fed. Cir. 2006) 5, 8
Anderson v. City of Bessemer City,
470 U.S. 564 (1985) 11
Calderon v. Thompson,
523 U.S. 538 (1998) 6
DyStar Textilfarben GmbH & Co. Deutschland KG . C.H. Patrick Co.,
464 F.3d 1356 (Fed. Cir. 2006) 8
Energy Capital Corp. v. United States,
302 F.3d 1314 (Fed.Cir.2002) 11
First Interstate Bank of Billings v. United States,
61 F.3d 876 (Fed. Cir. 1995) 11
Johnson v. Bechtel Assocs. Prof'l Corp., D.C.,
801 F.2d 412 (D.C. Cir. 1986) 6
KSR International Co. v. Teleflex Inc.,
550 U.S. __, No. 04-1350 (filed April 30, 2007). passim
One Lot Emerald Cut Stones and One Ring v. United States 409 U.S. 232 (1972) 7
Syngenta Seeds, Inc. v. Monsanto Co.,
No. 2006-1203 10
Syntex (U.S.A.) LLC v. Apotex, Inc.,
407 F.3d 1371 (Fed. Cir. 2005) 2
U.S. v. Tulare Lake Canal Co.,
677 F.2d 713 (9th Cir. 1982), *judgment vacated on other grounds*,
459 U.S. 1095 6
United States v. Adams,
383 U.S. 39 (1966) 9, 10

United States v. Kismetoglu,
468 F.2d 1386 (9th Cir. 1972) 7

RULES

Federal Circuit Practice Notes for Federal Circuit
Rule 35 5
Federal Circuit Rules
Rule 26(b) 4
Federal Circuit Rules
Rule 26(b)(1)(B) 4
Federal Circuit Rules
Rule 36 5
Federal Circuit Rules
Rule 40(e) 3
Federal Rules of Appellate Procedure
Rule 35(a) 10
Federal Rules of Appellate Procedure
Rule 35(b)(1)(A) 5
Federal Rules of Appellate Procedure
Rule 35(c) 3
Federal Rules of Appellate Procedure
Rule 36 ..... 3, 5
Federal Rules of Appellate Procedure
Rule 40 3
Federal Rules of Appellate Procedure
Rule 40(a)(1) 3, 4

INTRODUCTION

There is no reason for the Court to recall its mandate so that Apotex may file an untimely petition for rehearing. The Supreme Court's recent opinion in *KSR International Co. v. Teleflex Inc.* casts no doubt on the correctness of this Court's summary affirmance of the district court's judgment that Syntex's '493 patent is valid. The mere fact that *KSR* reversed a determination of nonobviousness that this Court reached on different facts in a different case does not amount to an "extraordinary circumstance" warranting the exceptional procedure of recall in *this* case. If the recall power were to be so lightly invoked, this Court would now find its docket overflowing with petitions for rehearing of every obviousness case decided over the past ten to twenty years.

To the extent there are cases which deserve rehearing in light of *KSR*, this is manifestly not one of them. The district court has already weighed Apotex's purported evidence of obviousness twice, and Apotex has already appealed to this Court twice. On the first appeal of this case, in 2004, this Court remanded to the district court with instructions to reconsider certain factual findings relating to the obviousness inquiry. On remand, the district court re-weighed the evidence and concluded once again that Syntex's patent was valid and nonobvious. Apotex appealed again, but, recognizing that this second appeal amounted to little more than a request for the appellate court to reweigh the evidence, this Court summarily affirmed pursuant to Federal Rule of Appellate Procedure 36.

The district court based its decision on, *inter alia*, two factual findings, neither of which is any less compelling in light of *KSR*. First, the district court found that the patented formulations performed in ways unexpected and unpredicted at the time they were made. Second, the district court found that, in addition to being firmly rebutted by the record, the opinions of Apotex's expert which formed the primary basis for Apotex's obviousness case were not

credible. These two findings, standing alone, were sufficient bases for the district court's conclusion of nonobviousness and for this Court's affirmance thereof. And *KSR* raises no question regarding either of them. *KSR*, therefore, does not amount to anything "extraordinary" with respect to this Court's summary affirmance of the district court's findings and conclusions. There is no reason for this Court's mandate to be recalled, or for Apotex to be afforded an opportunity to re-litigate issues that were not even the subject of the *KSR* decision.

BACKGROUND

Syntex (U.S.A.) LLC, now Roche Palo Alto LLC ("Syntex"), is the owner of U.S. Patent No. 5,110,493 ("'493 patent"). Allergan, Inc. is the exclusive licensee of the '493 patent. The '493 patent claims formulations and methods for treating eye inflammation and preservative systems for use in such formulations. Specifically, the patent claims the combination of a non-steroidal anti-inflammatory drug ("NSAID"), such as ketorolac tromethamine ("KT"), with Octoxynol 40 and a preservative, such as benzalkonium chloride ("BAC"), methods of using resulting formulations, and a preservative system including Octoxynol 40. Declaration of Nathan E. Shafroth In Support Of Appellees' Opposition ("Shafroth Decl."), Ex. 1 at JA 253-258; *see id.*, Ex. 1 at JA 71-73 (¶¶1-7).

On December 29, 2003, the U.S. District Court for the Northern District of California entered an order ruling that the '493 patent was valid, enforceable, and infringed by Apotex, Inc., Apotex Corporation, and Novex Pharma (collectively, "Apotex"). On May 18, 2005, this Court affirmed the district court on all issues except obviousness. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). The Court found error in several factual determinations underlying nonobviousness, and remanded for further consideration "in light of [its] corrections to the record." *Id.* at 1379.

On February 23, 2006, the district court held a hearing on the issue of nonobviousness. On June 2, 2006,

the district court issued findings of fact and conclusions of law, finding the '493 patent nonobvious and issuing a permanent injunction. Apotex appealed this decision as well, and on April 9, this Court summarily affirmed the district court's decision *per curium*, pursuant to Federal Rule of Appellate Procedure 36.

ARGUMENT

I. APOTEX HAS WAIVED ITS OPPORTUNITY TO PETITION FOR REHEARING OR FOR AN EXTENSION OF TIME.

The Federal Rules of Appellate Procedure clearly state that "a petition for . . . rehearing may be filed within 14 days after entry of judgment." Fed. R. App. Proc. 40(a)(1).[1] The Rules state just as clearly that—in the absence of such timely petition—"the court's mandate must issue 7 calendar days after the time to file a petition for rehearing." Over 21 days have passed since this Court entered judgment in favor of Syntex, and this Court's mandate has issued. Apotex may not move *now* to "extend" a deadline that has already expired.

Confronted with Rule 40(a)(1)'s clear dictate, Apotex chose to do nothing as two weeks passed from the time of this Court's judgment. Apotex was obviously aware that the Supreme Court's decision in *KSR* was forthcoming. Nonetheless, during the two-week window it was granted by the Federal Rules, Apotex did not move to stay this Court's mandate in this case pending the Supreme Court's decision in *KSR*, did not move for an extension of time in which to petition for rehearing, and did not petition for rehearing by the panel, or *en banc*. Instead, Apotex chose to wait past the

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[1] On its face, Rule 40 governs petitions for panel rehearings, but Federal Rule of Appellate procedure 35(c) states that Rule 40's timing requirements also govern petitions for rehearings *en banc*. Fed. R. App. Proc. 35(c). This Court's local rules defer to the Federal Rules on this point. *See* Fed. Cir. R. 40(e).

expiration of its deadline until *KSR* came down; only then did it move, essentially to have its failure absolved. The rules do not permit this.

As quoted above, the Federal Rules of Appellate Procedure very clearly require that any party who wishes to petition for rehearing do so within two weeks of judgment. While such a party may certainly move for an extension *prior* to the deadline for its petition, *see* Fed. Cir. R. 26(b), the Rules provide no mechanism for canceling this deadline once it has already passed.[2] This is unsurprising, since such a mechanism would render Rule 40(a)(1) a nullity.

The requirements of Rule 40(a)(1) are no mere technicality. Without some limit on a party's ability to file a motion or petition, or to move for an extension of time to do so, no issue (or case) would ever be finally decided. Apotex allowed *all* of the prescribed deadlines to lapse before raising any issue. Thus, *as far as the rules are concerned*, Apotex is no different than any of the hundreds of other parties who have come before this Court over the past ten to twenty years arguing that a patent was invalid for obviousness. Doubtless many of those parties also would contend that their cases would reach a different result if they were allowed another chance to argue obviousness in light of *KSR*. But if this Court were to fling open the floodgates and begin reopening pre-*KSR* obviousness cases, uncertainty and administrative disorder would ensue. The Supreme Court was surely cognizant of this potential danger when it stated that this Court had "no doubt" applied its TSM test in a manner consistent with the law in "many cases" in the past, and that further development of obviousness law should be left to this Court in "future cases." *KSR International Co. v. Teleflex*

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[2] Federal Circuit Rule 26(b)(1)(B), which Apotex cites as authority for its requested procedure, states that in "extraordinary circumstances," a party may file a motion to extend time less than seven days in advance of the deadline the movant requests to be extended. That rule does *not* state that, even under extraordinary circumstances, a party may wait until *after* a deadline has already passed before moving to "extend" it.

Inc., 550 U.S. __, No. 04-1350, slip op. at 15, 18 (filed April 30, 2007)

II. AS A RULE 36 SUMMARY AFFIRMANCE, THIS APPEAL IS AN ESPECIALLY POOR CANDIDATE FOR RECALL OF MANDATE AND REHEARING.

This Court affirmed the district court's determination of nonobviousness in a non-precedential order without opinion, pursuant to Federal Rule of Appellate Procedure 36. The Court's summary affirmance therefore embodied a determination that, given the nature of Apotex's appeal, "an opinion would have *no precedential value*." Fed. Cir. R. 36. In other words, in contrast to other obviousness cases decided during the time since the Supreme Court took review of *KSR*, *see, e.g., Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006), this Court found the issues involved in this case to be unexceptional. This determination belies Apotex's argument that *this case*, among all the obviousness cases decided by this Court prior to the Supreme Court's decision in *KSR*, is "extraordinary" and merits late rehearing.

In addition, because the Court's order in this case was filed without opinion, there is necessarily nothing on its face that could be inconsistent with *KSR*. And because the Court's order in this case is nonprecedential, it cannot cause any disuniformity with respect to other decisions within the Federal Circuit. As such, this case does not even qualify for *en banc* rehearing under the Federal Rule of Appellate Procedure upon which Apotex bases its proposed petition. *See* Rule 35(b)(1)(A) (requiring that the petition state that rehearing is "necessary to secure and maintain uniformity of the court's decisions"). It is no doubt for these reasons that this Court explicitly discourages petitions for *en banc* rehearings of appeals that have been subject to Rule 36 orders. Fed. Cir. Practice Notes for R. 35 ("A petition for rehearing en banc is rarely appropriate if the appeal was the subject of a nonprecedential opinion by the panel of judges that heard it."). To the extent any already-mandated obviousness case should be re-opened and reheard in light of

KSR, this is certainly not it.

III. THE SUPREME COURT'S *KSR* DECISION IS NOT AN "EXTRAORDINARY CIRCUMSTANCE" SUFFICIENT TO PROVOKE RECALL OF THE MANDATE IN THIS CASE

Even if Apotex's belated request for a recall of mandate and an extension of time were procedurally proper, Apotex's request would necessarily fail. The Supreme Court's decision in *KSR* has no effect on two key issues underlying the determination of nonobviousness in this case: the issue of unexpected results and the issues of witness credibility. Therefore, even the most expansive reading of *KSR* in Apotex's favor could not shake the validity of the patent at issue in this case. Accordingly, the issuance of *KSR* cannot constitute the type of "extraordinary circumstance" that Apotex must show here.

A. Legal Standard

Appellate courts' power to recall a mandate "can be exercised only in extraordinary circumstances." *Calderon v. Thompson*, 523 U.S. 538, 550 (1998). The recall power may only be used sparingly, and "may not be used simply as a device for granting late rehearing." *Johnson v. Bechtel Assocs. Prof'l Corp., D.C.*, 801 F.2d 412, 416 (D.C. Cir. 1986). Indeed, even "[a] change in controlling authority or a conviction that the court erred are ordinarily not alone sufficient grounds for recall of a mandate after final judgment." *U.S. v. Tulare Lake Canal Co.*, 677 F.2d 713, 715 (9th Cir. 1982), *judgment vacated on other grounds*, 459 U.S. 1095. The Supreme Court's recent decision in *KSR* does not represent a change in controlling authority that would have any effect on this Court's summary affirmance in this case; it is certainly not the type of "extraordinary circumstance" required for the exceptional relief Apotex seeks.

The type of extraordinary circumstance required for a

recall of mandate is well illustrated by the one case Apotex cites in its motions. In *United States v. Kismetoglu*, the Ninth Circuit was presented with a pure legal question: whether "in a criminal case where a judgment of acquittal had been ordered after a verdict of guilty by jury, the district court could enjoin the United States and its agents from filing a forfeiture action for an alleged violation of the custom laws." *Kismetoglu*, 476 F.2 269, 270 (9th Cir. 1973); *see United States v. Kismetoglu*, 468 F.2d 1386 (9th Cir. 1972). The Ninth Circuit answered this legal question in the affirmative. *Id.* Forty-two days later, in *One Lot Emerald Cut Stones and One Ring v. United States*, the United States Supreme Court resolved a Circuit split on this issue by holding that this *exact same legal question* must be answered in the negative. *One Lot*, 409 U.S. 232, 232 (1972) (affirming Fifth Circuit "holding that a forfeiture actuion . . . was not barred by an acquittal of charges of violating [customs laws]"). Because the Ninth Circuit's answer to the legal question presented in *Kismetoglu* ("yes") was exactly the opposite of the Supreme Court's answer to the same question in *Emerald Cut Stones* ("no"), the Ninth Circuit recalled its mandate. *Kismetoglu*, 476 F.2d 269, 270 (9th Cir. 1973).

The circumstances in this case are far different. Apotex presented this Court not with a pure legal question, but with several questions *all* relating to the propriety of *specific, factual determinations* made by the district court on the particular record of this case. Shafroth Decl., Ex. 1 at JA 5970-72. Even if *KSR* did represent a "sweeping change in the law of obviousness," as Apotex contends, Recall Mot. 2, it simply does not speak to the *factual* determinations made by the district court and summarily affirmed by this Court. Thus, with respect to this case, *KSR* represents nothing so "extraordinary" as to justify Apotex's requested relief.

B. This Court's Summary Affirmance of the District Court's Order Is Consistent with *KSR*

It is far from clear what effect (if any) the Supreme

Court's decision in *KSR* has on other cases concerning the obviousness of patented inventions—especially recent cases, such as this one, which were heard months after the Supreme Court granted certiorari and heard arguments in *KSR*. In its opinion, the Supreme Court explicitly "note[d] that the Court of Appeals ha[d] since elaborated a broader conception of the TSM test than was applied in the instant matter." *KSR*, No. 04-1350, slip op. at 17-18 (citing *DyStar Textilfarben GmbH & Co. Deutschland KG . C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006) and *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006)). This Court was operating under this "broader conception" in this case—the *Alza* case cited by the Supreme Court was also cited extensively by both parties in this case.

The Supreme Court did not criticize this Court's recent conception of its TSM test, or suggest that cases applying it ought to be reversed—much the opposite. Referring to such cases, the Supreme Court noted that "[t]he extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in *future cases*." *KSR*, No. 04-1350, slip op. at 18 (emphasis added); *see also id.* at 15 ("In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with [the principles laid out in *KSR*] in *many* cases.") (emphasis added). But even assuming (contrary to the Supreme Court's opinion) that this Court's recent conception of the TSM test is inconsistent with Supreme Court precedent, and that (contrary to the Supreme Court's opinion) this Court ought to reach back and re-analyze already-mandated decisions applying the more broadly-conceived TSM test, this Court's affirmance of the district court's decision in this case would remain correct. This is so for at least two reasons: *first*, as the district court correctly found, Syntex's patented formulation did not perform in a way that anyone at the time would have predicted; *second*, as the district court also found, the opinions of Apotex's expert which were the primary basis for Apotex's obviousness case were not credible.

1. *KSR* affirmed that unexpected results may render combination patents nonobvious.

In *KSR*, the Supreme Court reaffirmed the doctrine that "[t]he combination of familiar elements according to known methods is likely to be obvious *when it does no more than yield predictable results*." *Id.* at 12 (emphasis added). To "illustrate the application of this doctrine," the Supreme Court described its decision in *United States v. Adams*, 383 U.S. 39 (1966). *Id.* The combination patent in *Adams* differed from prior designs only by "the mere substitution of one element for another known in the field." *KSR*, No. 04-1350, slip op. at 12 (citing *Adams*, 383 U.S. at 50-51). Nonetheless, because the elements in the patented combination "worked together in an unexpected and fruitful manner," the Supreme Court in *Adams* "rejected the Government's claim that Adams's [patented invention] was obvious." *Id.*

On remand and on appeal, Apotex made the same argument made by the Government in *Adams*, and had this argument rejected for, *inter alia*, the same reason as the Supreme Court rejected it in *Adams*: it was unsupported by the record. Specifically, Apotex argued before the district court that "it is a maxim of patent law that in the absence of unexpected results, it is obvious to substitute one component of a chemical composition for a physically similar component," and that "absent 'unexpected results' from the use of [Octoxynol 40], its substitution for Polysorbate 80 in ophthalmic formulations is obvious as a matter of law." Shafroth Decl., Ex. 1 at JA 4991. But in a detailed factual analysis, the district court found that, in the context of Syntex's patented invention, Octoxynol 40 *did* show unexpected results by *far outperforming* Polysorbate 80 and the other non-ionic surfactants known at the time of Syntex's inventions. *Id.*, Ex. 1 at JA 82-85 (¶¶ 50-60) and JA 95-97 (¶¶101-109). As this Court recently reiterated in an opinion post-dating *KSR*, this set of findings was well within the power of the district court to make. *See Syngenta Seeds, Inc. v. Monsanto Co.*, No. 2006-1203, slip op. at 6 ("Whether the

degree of success is unexpected in light of suggestions in the prior art is a factual question."). And under *Adams* and *KSR*, these findings alone were sufficient to support the district court's determination that Syntex's patent is nonobvious.

Unsatisfied with this result, however, Apotex presented the exact same argument to this Court on appeal, arguing that the prosecution history supported a finding of obviousness "because the examiners repeatedly rejected the '493 claims stating that merely substituting one nonionic surfactant for another was not a patentable distinction without showing some unobvious result," Shafroth Decl., Ex. 2 at 27, and that "[t]he prior art provides a motivation to combine, in the absence of unexpected results," *id.*, Ex. 3 at 12. Given the district court's factual finding of unexpected results, however, this Court was apparently no more persuaded by these arguments than was the district court.

KSR does not suggest a different result. To the contrary, it reaffirms that a factual finding of unexpected results strongly favors a determination of nonobviousness. Nonetheless, Apotex spends nearly all of the substantive portion of its proposed petition for rehearing making its exact same "unexpected results" argument once again. Proposed Petition at 6-8. But Apotex's desire to re-litigate the issue of unexpected results based on the facts is no reason for a rehearing, *see* Fed. R. App. P. 35(a), much less an *extraordinary circumstance* justifying a recall of the mandate and *ex post* extension of time.

2. Legal Reasoning in *KSR* cannot render Apotex's expert's opinion credible.

The Supreme Court's opinion in *KSR* also did nothing to change the longstanding rule that "credibility determinations by the trial judge 'can virtually never be clear error.'" *First Interstate Bank of Billings v. United States*, 61 F.3d 876, 882 (Fed. Cir. 1995) (quoting *Anderson v. City of Bessemer City*, 470 U.S. 564, 575 (1985)). Yet Apotex would need such a rare ruling from this Court in order to

have any chance at prevailing on a rehearing of this case.

Nearly all of Apotex's purported evidence of obviousness rested on the testimony of its expert, Dr. Mitra. In findings affirmed by this Court, the district court found Dr. Mitra's opinions deficient, because they rested almost entirely on methodologically flawed experiments he conducted himself years after the time of Syntex's inventions, and because they were directly contradicted by other record evidence. Shafroth Decl., Ex. 1 at JA 86-89 (¶¶63-77). But the district court not only found Dr. Mitra's opinions unpersuasive on the issue of obviousness—it also explicitly found that Dr. Mitra's testimony was *not credible*. *Id.*, Ex. 1 at JA 89 (¶78). This finding by the district court was entitled to great weight on appeal. *See Energy Capital Corp. v. United States*, 302 F.3d 1314, 1329 (Fed. Cir. 2002) ("As for the relative weight given to the testimony of both sides' expert witnesses, we accord the trial court broad discretion in determining credibility because the court saw the witnesses and heard their testimony."). Therefore, when on appeal Apotex relied almost exclusively on Dr. Mitra's testimony again, this Court was correct to reject Apotex's arguments and affirm the district court. *KSR*, a case which had nothing to do with witness credibility, does not suggest otherwise. And, given that Dr. Mitra's testimony formed almost the entire foundation for Apotex's obviousness case before the district court, Apotex has no basis for arguing that the conclusion of nonobviousness should be overturned.

CONCLUSION

For the foregoing reasons, the Court should deny Apotex's motions for recall of mandate and *ex post* extension of time in which to petition for rehearing.

Dated: May 7, 2007

Respectfully submitted,

/s/ Alexander L. Brainerd
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Appeal No. 2006-1495

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC., APOTEX CORP., and NOVEX PHARMA

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA THE HONORABLE JUDGE MARTIN J. JENKINS
DISTRICT COURT CASE NO. CV 01-2214 MJJ

DEFENDANTS-APPELLANTS' REPLY TO APPELLEES' OPPOSITION TO APPELLANTS' MOTION TO RECALL AND STAY THE MANDATE, AND FOR EXTENSION OF TIME TO PETITION FOR REHEARING

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May 7, 2007

[CERTIFICATE OF INTEREST OMITTED]

TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

I. INTRODUCTION 1

II. ARGUMENT 1

A. Apotex Has Not Waived Its Opportunity to Petition for Rehearing or for an Extension of Time 1

B. A Rule 36 Summary Affirmance Does Not Detract from This Case's Candidacy for Recall of Mandate and Rehearing 2

C. *KSR* Gives Extraordinary Circumstances To Recall the Mandate 2

1. This Court Has Inherent Power To Recall its Mandate 2

2. This Court Summarily Affirmed a Decision Inconsistent with *KSR* 3

i. The District Court Erred Under KSR in Finding That a POSA Would Not Have Been Motivated to Substitute O_{40} For Polysorbate 80 3

ii. Alleged Unexpected Results Do Not Overcome the *Prima Facie* Showing of Obviousness Under *KSR* 7

III. CONCLUSION 10

I. INTRODUCTION

The Supreme Court's recent decision in *KSR International Co. v. Teleflex Inc.* provides ample reason why this Court should recall its mandate and grant Apotex' petition for rehearing. Syntex is mistaken that the holding in *KSR* does not give rise to extraordinary circumstances warranting recall of the mandate.

II. ARGUMENT

A. Apotex Has Not Waived Its Opportunity to Petition for Rehearing or for an Extension of Time

Under Fed.Cir.R. 26(b)(1), a motion for extension of time must generally be "made at least 7 calendar days before the date sought to be extended." However the Rules provide an exception whereby, "in extraordinary circumstances, a motion may be made *later than the deadlines prescribed in this rule*." Fed.Cir.R. 26(b)(1)(B) (emphasis added).

Rule 26(b)(1)(B) may be used to extend the 14 day deadline, even after that deadline has passed. *See Braniff Airways, Inc. v. Curtiss-Wright Corp.*, 424 F.2d 427, 429 (2d Cir. 1970) (court may enlarge time to petition for rehearing even if period has expired). Due to the extraordinary circumstances of the *KSR* decision, Apotex appropriately seeks to extend the date to petition for rehearing.

Syntex' argument that granting an extension of time renders Rule 40(a)(1) (governing petitions for rehearing) "a nullity," is a *non sequitur*. See Op. at 4. Syntex argues that if the motion were granted, it would "fling open the floodgates" *and invite* parties who have unsuccessfully sought to invalidate patents for obviousness to reopen their cases, it would cause "uncertainty and administrative

disorder." Op. at 4. This undue alarmism is based on Syntex' faulty assumption that under the Rules, Apotex is in the same position as the hundreds of others over the past decades that have argued that a patent is obvious. *Id.*

B. A Rule 36 Summary Affirmance Does Not Detract from This Case's Candidacy for Recall of Mandate and Rehearing

Syntex argues that since this Court rendered a non-precedential, summary affirmance, it attests to the Court's alleged view that this case is unexceptional. Op. at 5. This argument ignores that this Court's affirmance preceded the *KSR* decision, which renders combination patents such as the '493 patent substantially more vulnerable to a finding of obviousness. Thus, whether the Court considered this case "unexceptional" prior to *KSR* is irrelevant for present purposes.

C. *KSR* Gives Extraordinary Circumstances To Recall the Mandate

1. This Court Has Inherent Power to Recall its Mandate

An appellate court has the inherent power to recall its own mandate. *Zipfel v. Halliburton Co.*, 861 F.2d 565, 567 (9th Cir. 1988); *Sargent v. Columbia Forest Products, Inc.*, 75 F.3d 86, 89 (2d Cir. 1996). A supervening change in governing law is widely recognized as an "extraordinary circumstance" to warrant recall of an appellate court's mandate. *See Id.* at 90; *Zipfel*, 861 17.2d at 567; *Adkins v. Beech Aircraft Corp.*, 745 F.2d 1330, 1332 (11th Cir. 1984); *McGeshick v. A.K. Choucair*, 72 F. 3d 62, 63 (71° Cir. 1995). The *KSR* decision is inconsistent with this Court's affirmance. Recall of the mandate is appropriate. *See Zipfel v. Halliburton Co.*, 861 F.2d at 567-570 (Ninth

Circuit recalled mandate where Supreme Court decision "depart[ed] in some pivotal aspects" with the appellate court's decision).

2. This Court Summarily Affirmed a Decision Inconsistent with *KSR*

The fact that this Court did not render an opinion upon affirming the district court suggests only that this Court could not reverse the district court for clear error on the basis of its use of the pre-*KSR* application of the TSM test. Syntex asserts that Apotex asks this Court to reverse the district court's findings of fact. Rather, Apotex urges this Court to apply the TSM test in a flexible manner as *KSR* requires to the undisputed facts and evidence of record, as well as to facts found by this Court in its May 18, 2005 Order, which are part of the law of the case. *See State Indus., Inc. v. Mor-Flo Indus., Inc.*, 948 F.2d 1573, 1576 (Fed. Cir. 1991) (under the law of the case doctrine, "findings of fact reviewed in and relied upon in an appellate court's decision become law of the case ..."). In so doing, this Court will find the district court's determination of nonobviousness erroneous.

i. The District Court Erred Under *KSR* in Finding That a POSA Would Not Have Been Motivated to Substitute O_{40} For Polysorbate 80

The district court erred under *KSR* in neglecting to find motivation to combine O_{40} with the formulations disclosed in Waterbury, Gilbert and/or Han. For instance, the district court found a lack of motivation, in part, due to its determination that: "[T]here is no evidence that Octoxynol 40 was used in an ophthalmic product or formulation before the inventions of the '493 patent." District Court Opinion at p. 15, ¶ 49. This finding is

illustrative of the unduly rigid manner in which the district court applied the TSM test. In particular, this finding violates the *KSR* directive that motivation to combine may be found in "design incentives and other market forces ... either in the same field [as the patented invention] or a different one." *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (U.S. 2007). Since motivation may be found in *a different field altogether* from the patented product, it is of no consequence that O_{40} was not previously used in ophthalmics. In a similar vein, *KSR* rejected the assumption, "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." *Id.* at 1742. The Court explained that, "[c]ommon sense teaches that familiar items may have obvious uses beyond their primary purposes ...." *Id.*

This Court previously held that McCutcheon's, a directory of emulsifiers and detergents, teaches that O_{40} "was a known stabilizer." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1374-75 (Fed. Cir. 2005). During prosecution, the PTO rejected what became claim 1 of the '413 patent over McCutcheon's, because substituting O_{40} for other surfactants disclosed in Gilbert and Han was not a patentable distinction. (JA3482; JA3736). This Court held that an ordinary scientist ("POSA") knew that O_{40} was used in pharmaceuticals, and that McCutcheon's "cannot be so lightly overlooked." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d at 1380. Thus, regardless of whether O_{40} had previously been used in ophthalmics, *KSR* counsels that a POSA would use "common sense" in using the "familiar item" O_{40} for ophthalmics. *See KSR*, 127 S.Ct. at 1742.

"Structural relationships often provide the requisite motivation to modify known compounds to obtain new compounds." *In re Mayne*, 104 F.3d 1339, 1343 (Fed. Cir. 1997), *citing In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995). Here, a POSA would infer, from the "close structural

and chemical similarity" (JA1550-1551) of O_{40} to Polysorbate 80, that both compounds were "capable of solubilizing the KT/BAC complex by encapsulation." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d at 1382 n. 11. The structural similarity of O_{40} to Polysorbate 80 provides another source of motivation to combine, which the district court ignored.

The district court also rigidly applied the TSM test in holding that the primary prior art references, *i.e.*, Waterbury, Gilbert and Han, fail to "suggest, teach, or motivate use of Octoxynol 40 in an ophthalmic formulation ... whether examined in isolation or collectively ...". Opinion at p. 18, ¶ 62. This finding violates the *KSR* dictate that a motivation to combine need not be explicitly identified in the asserted references. Rather, courts are to view the TSM test, *from the perspective of a POSA*, who possesses knowledge beyond that disclosed within the four corners of the asserted references.

Throughout *KSR*, the Court articulated a multitude of sources from which a motivation to combine may be found, including, "the effects of demands known to the design community or present in the market place and the background knowledge possessed by a person having ordinary skill in the art." *KSR*, 127 S.Ct. at 1740. Moreover, the Court does not limit the TSM analysis to "precise teachings directed to the specific subject matter of the challenged claim." *Id.* at 1741. Rather, "a court can take account of the inferences and creative steps" that a POSA would make. *Id.* Citing *KSR* in a recent decision, this Court noted that "the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others were not." *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 2007 WL 1345333 at *4 (May 9, 2007). *KSR* therefore rejects the "overemphasis on the importance of published articles and the explicit content of

issued patents," since often there will be little published "discussion of obvious ... combinations." *KSR*, 127 S.Ct. at 1742. *KSR* also explained that "[u]nder the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* In determining that there was no teaching, suggestion or motivation to substitute O_{40} for polysorbate 80, the district court evinced a strict reliance on the existence of motivation in the asserted references themselves, clearly in violation of *KSR*.

KSR rejected the notion that "obvious to try is *per se* an improper standard by which to assess obviousness:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103:

KSR at 1742. The "obvious to try" test articulated in *KSR* further demonstrates the error the district court committed by rigidly applying the TSM test and failing to find a motivation to combine.

A reexamination of the record at the district court reveals that there was a definite motivation to use O_{40} as a surfactant in the formulations disclosed in the prior art. The court therefore .erred in finding that Apotex had not made out a *prima facie* case of obviousness. *See Tec Air, Inc.*

v. Denso Mfg. Michigan Inc., 192 F.3d 1353, 1359 (Fed. Cir. 1999) (*prima facie* obviousness established where objective teaching in the prior art or knowledge of a POSA would lead the POSA to combine relevant teachings of asserted references)

ii. Alleged Unexpected Results Do Not Overcome the *Prima Facie* Showing of Obviousness Under *KSR*

A *prima facie* showing of obviousness may be rebutted by demonstrating that the patented invention achieved unexpected results, *i.e.*, "some superior property or advantage that a [POSH] would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Where, as here, the allegedly "unexpected results" are highly questionable, they cannot rebut the *prima facie* showing of obviousness. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007) ("[E]ven if Pfizer showed ... unexpectedly superior results, this secondary consideration does not overcome the strong showing of obviousness.").

In its May 18, 2005 Order, this Court found that "this case is unusual because certain key facts existed that give rise to some doubt as to the strength of the factual proposition that O_{40} indeed produced unexpected results." *Syntex*, 407 F.3d at 1383. This Court similarly stated, "[W]e think the district court failed to appreciate that the prosecution history of the relevant patents ... casts some doubt on the final examiner's conclusion that the claimed surfactant produces unexpected results sufficient to overcome a prima facie case of obviousness." *Id.* at 1379. Syntex supported its claim of unexpected results with test results disclosed in the highly suspect Lidgate Declaration. This Court questioned the veracity of the Lidgate Declaration due to omitted data showing that $O_{12.5}$ performed

comparably to O_{40}. The Lidgate Declaration tried to show that O_{40} was unexpectedly superior to other octoxynols. *Id.* at 1382-83. Despite this Court's skepticism regarding Syntex' claim of unexpected results and this Court's charge to the district court to reevaluate unexpected results, the district court nonetheless found that Syntex had demonstrated unexpected results.

The district court's finding, however, is predicated on an erroneously abridged version of Dr. Mitra's Expert Report. Upon Plaintiffs' Motion during the remand, the district court excluded portions of the Report (JA71 n. 1) after this Court had already analyzed and considered the Report (JA2729-2949) in the previous appeal. (JA220-222). In particular, the district court deemed only certain pages and exhibits of the Report to be part of the trial record. (JA71 n. 1). This was a clear error of law.

Parties have an obligation to raise any issues regarding the content of the record in the district court *before* the appeal is decided. *See Fed. R. App. P.* 10(e); *Zimmerman v. Chicago Bd. of Trade*, 360 F.3d 612, 622 (7th Cir. 2003).

In its May 18, 2005 Order, this Court asked the district court to consider Dr. Mitra's testimony and his Report on obviousness and unexpected results. (JA220- 222). This Court referred globally to the entire Report, and offered specific cites to it. (JA220-222). However, on remand the district court erroneously considered only the small portion of the Report that the district court improperly deemed to be admitted. (JA71 n. 1). The district court's truncated reevaluation of the Report was error and contrary to this Court's mandate, which this Court issued after considering the entire Report. The district court erred as a matter of law by rendering a decision without considering the entire Report as this Court had done, because the decision of an appellate

court on an issue of law becomes the law of the case on remand. Moore's Federal Practice §134.23[1][a] (2003); *United States v. Garcia-Beltran*, 443 F.3d 1126, 1130 (9th Cir. 2006).

Apotex respectfully urges this Court to reconsider whether the '493 patent is obvious in light of a reevaluation to combine under *KSR* and Syntex' showing of alleged unexpected results was sufficient to preserve the validity of the '493 patent.

III. CONCLUSION

For these reasons, Apotex respectfully requests that this Court recall its mandate and grant Apotex' Petition.

Respectfully submitted,

May 16, 2006

By /s/ Robert S. Silver

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